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ARTICLE

Judicial Review of Compliance with the Precautionary Principle from *Paraquat* to *Blaise*: “Quantitative Thresholds,” Risk Assessment, and the Gap Between Regulation and Regulatory Implementation

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Abstract

This Article frames the precautionary principle as an *inner limit* to the EU institutions’ broad discretion in the field of EU risk regulation, contextualizing recourse to the principle against the more encompassing backdrop of socially acceptable risk approaches. On these grounds, it inquires to what extent the precautionary principle may be successfully invoked in challenges to acts which are deemed insufficiently protective. The opening sections set the ground for the analysis. The third section analyzes challenges to regulatory acts, arguing that the Court has followed a *quantitative threshold* approach. This is legally tenable and appropriate; however, it cannot do justice to the true nature of the precautionary principle. The following sections analyze cases involving legislative acts. This includes an in-depth examination of the recent *Blaise* case, which has put judicial review of compliance with the precautionary principle under the spotlight. Against this overall background, this Article concludes that judicial review can hardly do justice to the precautionary principle, as applicable to the risk management process and underpinning EU legislative frameworks. It will ultimately rest on EU risk managers and EU legislators to ensure that the principle is applied and that its overarching goals are pursued.

Keywords Precautionary Principle; risk regulation; judicial review; Court of Justice of the European Union; administrative discretion; pesticides; PPP Regulation; *Blaise*; genetically modified organisms; Confédération Paysanne

A. Introduction

This Article frames the precautionary principle as an *inner limit* to the EU institutions’ broad discretion in the field of EU risk regulation, contextualizing recourse to the principle against the more encompassing backdrop of socially acceptable risk approaches. On these grounds, it inquires to what extent a breach of the precautionary principle may be successfully invoked in challenges to regulatory and legislative acts which are deemed insufficiently protective.

The opening sections set the grounds for the analysis, providing an overview of the precautionary principle in the context of EU risk regulation and EU judicial review. The third section

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analyzes judicial review of compliance with the precautionary principle in challenges to regulatory acts. Drawing on an analysis of *Paraquat*¹ and *France v. Commission*,² this Article argues that the Court of Justice of the European Union has followed a “quantitative threshold” approach. This is both legally tenable and appropriate. By employing this approach, the Court has drawn some boundaries between judicial review of compliance with the precautionary principle, on the one hand, and an acknowledgment of the risk manager’s discretion in complying with the precautionary principle, on the other hand. However, this approach cannot do justice to the true nature of the principle. Normative and political contestation as to whether uncertain risks are socially acceptable and worth running lies at the heart of precautionary principle; yet, the Court will refrain from engaging with this qualitative aspect. This is the slippery slope of the precautionary principle that the Court has carefully, and understandably, avoided.

The fourth and fifth sections analyze cases where the precautionary principle has been used as a sword³ in challenges involving legislative acts. The fourth section provides an overview of *Monsanto Italia*⁴ and *Confédération Paysanne*.⁵ The fifth section conducts an in-depth examination of the recent *Blaise*⁶ case, which has put judicial review of compliance with the precautionary principle under the spotlight. This Article finds that these cases have yielded mixed results. The Court may find that a legislative act is in breach of the precautionary principle where it has robust legal elements to draw this conclusion. However, it has also suggested that issues pertaining to procedural regulatory arrangements, the scope of risk assessment, or the distribution of regulatory authority should primarily be dealt with by the EU legislator and solved in the political arena. Further, regulatory implementation issues might be more salient than legal matters in cases involving legislative frameworks. This scenario is perfectly exemplified by the highly complex implementation matters at stake in *Blaise*. Where this occurs, a challenge on the basis of the precautionary principle will be useless. Regulatory implementation is neither a matter of law, nor for the Court to review.

Against this overall background, the Article concludes that judicial review can hardly do justice to the precautionary principle, as applicable to the risk management process and underpinning EU legislative frameworks. The difficulties that the Court faces in its legal examination are inherent to the nature of the principle. On these grounds, it will rest on EU risk managers and EU legislators to ensure that the precautionary principle is applied and that its overarching goals are pursued.

B. The Precautionary Principle and EU Risk Regulation

The precautionary principle and its role, overarching tenets, and implications has intrigued academic commentators for years.⁷ Its application to risk management and societal and political

¹CJEU Case T-229/04, *Sweden v. Commission*, ECLI:EU:T:2007:217 (July 11, 2007), [hereafter *Paraquat*].

²CJEU, Case T-257/07, *France v. Commission*, ECLI:EU:T:2011:444 (Sept. 9, 2011), See also CJEU, Case C-601/11 P, *France v. Commission*, ECLI:EU:C:2013:465 (July 11, 2013), (wherein the party appealed, though unsuccessfully).

³The reference to the use of the precautionary principle as a “shield” and a “sword” is borrowed from Joanne Scott & Ellen Vos, *The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle Within the EU and the WTO*, in *GOOD GOVERNANCE IN EUROPE’S INTEGRATED MARKET* 253 (Christian Joerges & Renaud Dehousse eds., 2002).

⁴CJEU, Case C-236/01, *Monsanto Agricoltura Italia and others*, ECLI:EU:C:2003:431 (Sept. 9, 2003), [hereafter *Monsanto Italia*].

⁵CJEU, Case C-528/16, *Confédération Paysanne and others v. Premier Ministre and Ministre de l’Agriculture, de l’Agroalimentaire et de la Forêt*, ECLI:EU:C:2018:583 (July 25, 2018), [hereafter *Confédération Paysanne*].

⁶CJEU, Case C-616/17, *Blaise and others*, ECLI:EU:C:2019:800 (Oct. 1, 2019).

⁷In EU law, see, Marjolein Van Asselt & Ellen Vos, *The Precautionary Principle and the Uncertainty Paradox*, 9 J. OF RISK RES. 313 (2006); Maria Lee, *Beyond Safety? The Broadening Scope of Risk Regulation*, 62 CURRENT LEGAL PROBS. 242 (2009); ELLEN VOS & MICHELLE EVERSON, *UNCERTAIN RISKS REGULATED* (2012); Elizabeth Fisher, *Framing Risk Regulation: A Critical Reflection*, 4 EUR. J. RISK REG. 125 (2013); Christopher Anderson, *Contrasting Models of EU Administration in Judicial Review*

controversies surrounding the precautionary nature of risk regulation have been under the spotlight for a long time.⁸ Yet, legal analysis still struggles to capture what has been defined as the “juridification of uncertainty.”⁹

Under EU law the precautionary principle is enshrined, yet not defined, in the TFEU.¹⁰ Several references to the principle that a high level of public health and environmental protection shall be pursued in the Union may also be identified therein.¹¹ All legislative frameworks in the field of EU risk regulation are underpinned by the precautionary principle,¹² yet the only definition is found in Article 7(1) of the General Food Law. This Article stipulates that,

[I]n specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the [Union] may be adopted, pending further scientific information for a comprehensive risk assessment.¹³

A more encompassing and more detailed definition is provided for under the 2001 Commission Communication on the Precautionary Principle. The Communication draws a distinction between the two limbs of the principle:¹⁴ the decision *whether* to act in the face of persisting uncertainty, and the decision of *how* to act, weighing and balancing all relevant interests at stake, considering alternative regulatory options and enacting specific risk management measures. In respect of the *whether* to act limb, the 2001 Communication maintains that the precautionary

of *EU Risk Regulation*, 51 COMMON MKT. L. REV. 424 (2014); MARIA WEIMER & ANNIEK DE RUIJTER, *REGULATING RISKS IN THE EUROPEAN UNION* (2019). In U.S. law, see, SHEILA JASANOFF, *DESIGNS ON NATURE: SCIENCE AND DEMOCRACY IN EUROPE AND THE UNITED STATES* (2005); CASS SUNSTEIN, *LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE* (2005). In the WTO context, see, JOANNE SCOTT, *THE WTO AGREEMENT ON SANITARY AND PHYTOSANITARY MEASURES: A COMMENTARY* (2009); Christian Joerges & Alexia Herwig, *The Precautionary Principle in Conflicts Law Perspective*, in *RESEARCH HANDBOOK ON ENVIRONMENT, HEALTH AND THE WTO* 3 (Geert Van Calster & Denise Prévost eds., 2013). From the broader public international law perspective, see JACQUELINE PEEL, *SCIENCE AND RISK REGULATION IN INTERNATIONAL LAW* (2010).

⁸For an overview of risk management in the highly controversial field of genetically engineered organisms, see MARIA WEIMER, *RISK REGULATION IN THE INTERNAL MARKET: LESSONS FROM AGRICULTURAL BIOTECHNOLOGY* (2019), and Giulia Claudia Leonelli, *The Perfect Storm: GMO Governance and the EU Technocratic Turn*, in *RESEARCH HANDBOOK ON EU ENVIRONMENTAL LAW* 364 (Marjan Peeters & Mariolina Elia Antonio eds., 2020). On the glyphosate controversy, see Giulia Claudia Leonelli, *The Glyphosate Saga and the Fading Democratic Legitimacy of EU Risk Regulation*, 25 MAASTRICHT J. EUR. & COMP. L. 582 (2018).

⁹See Scott & Vos, *supra* note 3.

¹⁰Consolidated Version of the Treaty on the Functioning of the European Union, art. 191(2), May 9, 2008, 2008 O.J. (C115) 47 [hereafter TFEU].

¹¹References to the principle that a high level of public health and environmental protection shall be ensured are ubiquitous in the Treaties, starting from TFEU art. 114(3) & 191(2).

¹²In legislative acts, see Commission Regulation 178/2002 of 28 January 2002 Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority, and Laying Down Procedures in Matters of Food Safety, 2002 O.J. (L 31) 1, recital (21), arts. 6(3), 7(1) [hereinafter *The General Food Law*]; Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC, O.J. 2001 (L 106) 1 recital (8), arts. 1(1), 4(1) [hereinafter *Deliberate Release Directive*]; the cross-references to the General Food Law, including the notion of the precautionary principle enshrined therein, in art. 7(1) of Commission Regulation 1829/2003 of 22 September 2003 on Genetically Modified Foods 2003 O.J. (L 268) 1 art. 7(1) [hereinafter *GM Food and Feed Regulation*]; Commission Regulation 1107/2009/EC of 21 October 2009 Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC, 2009 O.J. (L 309) 1 recital (8), arts. 1(4), 13(2) [hereinafter *PPP Regulation*]; Commission Regulation 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) and Establishing a European Chemicals Agency (ECHA) and Amending Directive 1999/45/EC and repealing Council Regulation (EEC) 793/93 and Commission Regulation (EC) 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, 2006 O.J. (L 396) 1 recitals (9), (69), art. 1(3).

¹³See *GM Food and Feed Regulation* art. 7(1) (referencing *General Food Law*).

¹⁴*Commission Communication on the Precautionary Principle*, at 12, COM (2000) 1 final (Feb. 2, 2000).

principle may apply where “scientific information is *insufficient, inconclusive, or uncertain* and where there are indications that the *possible effects* on the environment or human, animal or plant health may be potentially dangerous and *inconsistent with the chosen level of protection*.”¹⁵

This definition is broader and arguably more accurate than the one found in the General Food Law. First, it can encompass all forms of scientific uncertainty. In risk regulation, a “hazard” is defined as a biological, chemical, or physical agent with the potential to cause adverse effects.¹⁶ A “risk,” on the other hand, is defined as the probability of occurrence of adverse effects and their severity, as resulting from exposure to a hazard.¹⁷ Uncertainties surface at each and every stage of the technical-scientific evaluation (risk assessment) process, and can be categorised as “hazard-related,” “risk-related,” and “methodological” uncertainties.¹⁸

The typical precautionary principle scenario involves absence of conclusive scientific proof of specific adverse effects in circumstances where a causal link between the potentially hazardous characteristics of a product or process and adverse effects cannot be positively established; in other words, science can neither confirm nor exclude the possibility of adverse effects. These cases involve hazard-related uncertainties.¹⁹ However, scientific uncertainty may also relate to exposures and the evaluation and characterization of relevant risks. Questions relating to exposures in real life conditions or multiple exposures may be at stake. Further, in the face of data gaps or diverging results in different scientific studies, the available evidence may be considered insufficient for the purposes of characterizing complex risks and ascertaining whether they meet the intended level of protection.²⁰ These are forms of risk-related uncertainty. Finally, the application of different models and methods, yielding different results, may come into play. This generates methodological uncertainties, insofar as reliance on different data will result in different risk management measures.²¹ Quite clearly, the broad definition enshrined in the 2001 Communication may encompass within its scope all these forms of uncertainty.

Second, the definition in the 2001 Communication highlights the connection between the determination of the *intended level of protection*, the identification of the *threshold of acceptable risk*, and recourse to the *precautionary principle* in a very clear way. The precautionary principle applies where, in the face of *uncertainty*, a risk may be *too high* to comply with the *level of protection* set by the risk manager. Thus, the decision on whether to act “is a function of the risk level that is *acceptable* to the society on which the risk is imposed.”²² This is explicitly acknowledged to be “an *eminently political* decision.”²³

The case law of the Court has generally drawn on these definitions in cases where the precautionary principle is at stake.²⁴ However, as illustrated in the following sections, the Court’s case law

¹⁵*Id.* at 7, 12.

¹⁶*Id.* at 28 annex III.

¹⁷*Id.*

¹⁸For an in depth analysis, see GIULIA CLAUDIA LEONELLI, TRANSNATIONAL NARRATIVES AND REGULATION OF GMO RISKS (forthcoming 2021); see also Giulia Claudia Leonelli, *Acknowledging the Centrality of the Precautionary Principle in Judicial Review of EU Risk Regulation: Why it Matters*, 57 COMMON MKT. L. REV. 1773 (2020).

¹⁹Prominent examples are genetically engineered organisms, glyphosate’s carcinogenicity, or the uncertain public health risks posed by residues of hormones—administered for growth promotion purposes—in meat. See LEONELLI, *supra* note 18. Hazard-related uncertainties may also emerge at the hazard characterization stage.

²⁰These aspects emerge quite clearly in the field of pesticides; see *infra*, Section F. See also LEONELLI, *supra* note 18.

²¹This is typical of the regulation of chemicals. See, e.g., the analysis in Giulia Claudia Leonelli, *The Fine Line Between Procedural and Substantive Review in Cases Involving Complex Technical-Scientific Evaluations: Bilbaina*, 55 COMMON MKT. L. REV. 1217 (2018) (providing an annotation of ECJ, Case C-691/15 P, European Commission v. Bilbaina de Alquitranes SA and others, ECLI:EU:C:2017:882 (Apr. 22, 2020)).

²²Commission Communication on the Precautionary Principle, *supra* note 14, at 15.

²³*Id.*

²⁴The case law of the Court mostly relates to challenges against acts which are deemed *too restrictive*; see *infra*, the analysis in Section C. For the first oblique reference to the precautionary principle in the Court’s case law, preceding the adoption of the Commission Communication, see Opinion of Advocate General Szpunar at paras. 63, 64, Case C-157/96, Ex parte

in the field of EU risk regulation mostly focuses on the risk manager's broad margins of discretion. The notion of administrative discretion, as such and as unqualified by further indications, is unrelated to the overarching tenets of the precautionary principle and the pursuit of a high level of protection.²⁵ In this sense, the acknowledgement of the risk manager's broad discretion limits the opportunities to challenge EU acts on the grounds of a breach or misapplication of the precautionary principle.

Against this backdrop, can *compliance with the precautionary principle* be the object of judicial review in cases where an act is challenged for being *insufficiently protective*? If the answer is *affirmative*, why and how is this possible? Regulatory theory provides some relevant insights in this respect. As the following subsection endeavours to show, the precautionary principle can be framed as an inner limit to the EU institutions' broad discretion. In fact, regulatory theory sheds some light on the role of the precautionary principle and its relationship to the notion of administrative discretion. However, for the purposes of this analysis, the precautionary principle must be set against the broader picture of socially acceptable risk approaches.²⁶ In other words, the precautionary principle cannot be analyzed in isolation.

I. Putting the Precautionary Principle Into Context: Socially Acceptable Risk Approaches and The Question of Administrative Discretion

The interconnections between *prudential* approaches to risk assessment²⁷ and multiple forms of *scientific uncertainty*, on the one hand, and precautionary risk management,²⁸ on the other, are too often neglected. A prudential approach to risk assessment entails that hazard-related, risk-related, and methodological uncertainties should be taken into due consideration. Prudential models and safety factors, which are most likely to over-estimate the relevant risks, should be employed. Further, risk assessments should be as thorough and all-encompassing as technically possible, with a view to dispelling persisting uncertainties.²⁹ Framing precautionary risk management in isolation from the notions of uncertainty, scientific complexity, and scientific pluralism has resulted in the assumption that recourse to the precautionary principle is "non-scientific." Yet, as this section illustrates, this is far from being the case.

Further, other legitimate factors (OLFs) and their importance within risk management are hardly given the attention they deserve in risk regulation theory. These encompass public opinion and public perception of risk, the availability and effectiveness of risk management measures, and an evaluation of the advantages, disadvantages, and distributional implications associated with the

National Farmers' Union and Others (June 2, 2016) ("[W]here there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent."); For further elaboration, following the Commission Communication, see CJEU, Case T-13/99, Pfizer Animal Health SA v. Council, ECLI:EU:T:2002:209 (Sept. 11, 2002), paras. 142–146; CJEU, Case T-70/99, Alpharma v. Council, ECLI:EU:T:2002:210 (Sept. 11, 2002), paras. 153–55; CJEU, Joined Cases T-74, 76, 83, 85, 132, 137 & 141/00, Artegodan and Others v. Commission, ECLI:EU:T:2002:283 (Nov. 26, 2002), para. 184, [hereinafter *Artegodan and Others*].

²⁵For in-depth insight on this point, set against the analysis of challenges to acts which are deemed too restrictive, see Leonelli, *Acknowledging the Centrality of the Precautionary Principle in Judicial Review of EU Risk Regulation: Why it Matters*, *supra* note 18.

²⁶For an overview of socially acceptable risk approaches, see Leonelli, *Transnational Narratives and Regulation of GMO Risks*, *supra* note 18; Leonelli, *The Perfect Storm: GMO Governance and the EU Technocratic Turn*, *supra* note 8.

²⁷The risk assessment stage consists of a technical-scientific evaluation of uncertain risks, conducted by experts. For a definition, see General Food Law, *supra* note 12, at arts. 3(11), 6(2). For references to "prudential" risk assessment, see *Commission Communication on the Precautionary Principle*, *supra* note 14, at 12.

²⁸Risk management consists of the determination of the intended level of protection, setting of the threshold of acceptable risk, and enactment of risk management measures. For a definition, see General Food Law, *supra* note 12, at arts. 3(12), 6(3).

²⁹For an in depth analysis of the notion of a "prudential" risk assessment, see Leonelli, *Transnational Narratives and Regulation of GMO Risks*, *supra* note 18.

decision to run uncertain risks and different regulatory options.³⁰ While OLFs are conceptually distinguished from the precautionary principle, a close connection exists between the two.

Ultimately, the precautionary principle is embedded in a broader, “socially acceptable risk” approach to risk governance. Under this ideal model, uncertain risks should only be run where they are deemed socially acceptable, taking into due account *scientific uncertainty*, the *intended level of protection*, the overarching tenets of the *precautionary principle*, and any relevant OLFs.³¹ Considerations as to the specific—public health and environmental—values at stake and the pervasiveness and irreversibility of any potential adverse effects pertain to the application of the precautionary principle. However, all elements—scientific uncertainty, intended level of protection, precautionary principle, and OLFs—are set along a continuum under iterative,³² socially acceptable risk approaches.

This does not mean that reliance on socially acceptable risk approaches will always result in the pursuit of a zero risk threshold and the implementation of bans or restrictive measures. High risks might be considered socially acceptable, while lower risks might not. Rather, it means that considerations as to *whether* and *why* uncertain risks are acceptable should be taken into due consideration in setting the threshold of socially acceptable risk.³³ A further implication is that risk regulation will be open to political and societal debate about the level of protection pursued, the reasons why uncertain risks are—or are not—worth running, and the distributional implications of regulatory measures. In regulatory terms,³⁴ the EU system of risk governance draws on socially acceptable approaches.

By contrast, ideal evidence-based regulatory models reflect the hegemonic narrative on risk governance, whereby uncertain risks must be taken *as long as* specific adverse effects have not been scientifically established³⁵ or *insofar as* this regulatory option is cost-benefit effective.³⁶ Evidence-based approaches postulate a *sound scientific*—rather than prudential—approach to risk assessment, and adherence to *sound science*. Regulatory focus on persisting uncertainty is bound to be limited; from a sound scientific perspective, positive scientific proof of the existence of a specific hazard and materialisation of a risk is the precondition for regulation.³⁷

Reliance on the results of sound risk assessments and adherence to sound science are economically cost-benefit effective in and of themselves; quite intuitively, they relieve market actors from the regulatory burdens and economic costs associated with more cautious approaches. In this sense, they *indirectly* reflect the pursuit of a cost-benefit effective level of protection. And indeed, in cases where hazards and risks have been conclusively established, economic cost-benefit analysis will come into play *directly*.³⁸ Cost-benefit analysis heuristics, based on the calculation of an aggregate value of expected wealth maximization, apply to risk management. Risk regulation should only be enacted insofar as the relevant expected public health and environmental benefits outweigh the economic costs associated with regulation. The legally relevant threshold of risk is determined *by means of* economic cost-benefit analysis. All in all, the adverse effects of a product

³⁰See also Leonelli, *The Perfect Storm: GMO Governance and the EU Technocratic Turn*, *supra* note 8; Leonelli, *The Glyphosate Saga and the Fading Democratic Legitimacy of EU Risk Regulation*, *supra* note 8. For a reference to OLFs, see *supra* note 14, at 19. In EU legislation, see General Food Law, *supra* note 12, at recital (19), arts. 3(12), 6(3).

³¹Leonelli, *Transnational Narratives and Regulation of GMO Risks*, *supra* note 18.

³²On the notion of “iterative” approaches to risk regulation, see Fisher, *supra* note 7.

³³For a reflection on the implications of different approaches to risk regulation and the reasons why uncertain risks ought to be taken, see Lee, *supra* note 7.

³⁴Although not always or not necessarily in terms of regulatory implementation—for controversial cases, see *supra* note 8.

³⁵E.g., regardless of persisting uncertainty on the existence of hazards or materialization of risks. See Leonelli, *Transnational Narratives and Regulation of GMO Risks*, *supra* note 18.

³⁶E.g., in cases where hazards and risks have been conclusively established see *id.*

³⁷For a detailed analysis of these points, see *id.*

³⁸For an in depth analysis, see *id.*

or process should not be “unreasonable” or “excessive,” taking into account the economic benefits associated with the product or process as well as the economic costs of regulation.³⁹

This overview triggers two considerations. The first and more general consideration relates to the two ideal approaches and their nature, whereas the second and more specific reflection pertains to the relationship between the precautionary principle and the notion of administrative discretion. Starting from the first and broader consideration, an analysis through the lens of evidence-based and socially acceptable risk approaches demonstrates that the identification of the threshold of *legally relevant* adverse effects is *never* a matter of “pure” science.⁴⁰ Rather, the determination of the threshold of risk triggering regulatory intervention results from three factors.⁴¹ The first factor consists of recourse to *more or less prudential approaches* to risk assessment. The second factor is the extent to which regulators focus on *sound science* or *uncertainties* surrounding the existence of hazards or the materialization of risks, and take into consideration the perceived insufficiency of the available evidence. The third factor is the *level of protection* pursued by regulators, and the *specific factors* that they may take into account for the purposes of decision-making. These are the *normative frames* which directly or indirectly inform the entire risk regulation process.⁴² Under evidence-based models, regulators are bound to pursue an *economically cost-benefit effective* level of protection. Under socially acceptable risk approaches, by contrast, the intended level of protection may be *higher*. Further, *OLFs* may be taken into account and feed into the determination of the threshold of acceptable risk.

Against this backdrop, the dichotomy of allegedly neutral and objective sound scientific approaches versus politicized precautionary risk management neither does justice to the reality of *scientific complexity*, nor to the *normative frames* at play in the risk governance process. The twofold assumption that sound scientific approaches *must* be adhered to and that sound science *must* be relied on is *informed by non-scientific* considerations surrounding regulatory cost-benefit effectiveness, just like consideration of *non-scientific* OLFs and the desire to pursue enhanced levels of protection are reflected in recourse to prudential approaches and a focus on persisting uncertainty.⁴³ Neither regulatory model is neutral and objective.

A similar dichotomous construction surfaces in cases where both hazards and risks have been conclusively established. In these cases, stringent regulatory standards are alleged to result from a focus on hazards, rather than risks,⁴⁴ suggesting that regulators irrationally focused on the hazardous properties of a product—“hazard,” rather than on the probability of occurrence of adverse effects and their severity—“risk.” Clearly, this is unlikely to be the case.⁴⁵ Diverging regulatory standards in these instances result from a *different evidence base* (more or less prudential risk assessments), from *different perspectives* on scientific uncertainties and scientific insufficiency, and from the pursuit of *different levels of protection*. Indeed, even in cases where uncertainties are not salient, the threshold of acceptable risk is bound to vary if the intended level of protection diverges. Adverse effects which are considered “negligible,” “acceptable,” or not “unreasonable” in some jurisdictions may be differently evaluated in other legal systems.⁴⁶

The second and more specific consideration, as noted above, pertains to the relationship between the precautionary principle and the notion of administrative discretion. In legal systems drawing on evidence-based models, risk governance functions are allocated to regulatory—

³⁹*Id.*

⁴⁰This sentence and terminology is borrowed from Vern R. Walker, *The Myth of Science as a ‘Neutral Arbiter’ for Triggering Precautions*, 26 B.C. INT’L & COMP. L. REV. 197, 198 (2003).

⁴¹For an in depth analysis, see Leonelli, *Transnational Narratives and Regulation of GMO Risks*, *supra* note 18.

⁴²*Id.*

⁴³*Id.*

⁴⁴For an example of this reductionist perspective, see Ragnar E. Lofstedt, *Risk Versus Hazard: How to Regulate in the 21st Century*, 2 EUR. J. RISK REG. 149 (2011)..

⁴⁵See *infra*, Section F, for a reference in the context of the analysis of the PPP Regulation.

⁴⁶Leonelli, *Transnational Narratives and Regulation of GMO Risks*, *supra* note 18.

technical-scientific—agencies; these are in charge of risk assessment as well as risk management.⁴⁷ The results of sound scientific risk assessment and evaluations surrounding economic cost-benefit effectiveness are all that should inform regulatory responses. Accordingly, authority lies with technical experts. From this perspective, under evidence-based approaches, administrative discretion is ultimately curtailed by the need to adhere to sound science and conform to the overarching tenets of cost-benefit analysis.

Conversely, in the EU legal system, risk assessors are only responsible for informing the technical-scientific knowledge of political risk managers; this reflects the rationale and goals of socially acceptable risk approaches. Final decision-making rests with risk managers, who are in charge for setting the threshold of socially acceptable risk and who are endowed with broad discretionary powers. The superiority of political and democratic legitimacy over functional legitimacy—technical expertise—shines through socially acceptable risk approaches.⁴⁸ However, a comparison between the institutional framework of EU risk governance and different regulatory models triggers one further, important consideration.

For the purposes of the present inquiry, a contextual analysis of systems influenced by evidence-based and socially acceptable risk approaches shows that the EU institutions' broad discretionary powers *stem from* the need to take the precautionary principle and OLFs into account in the determination of the threshold of acceptable risk. Indeed, if the precautionary principle and OLFs were irrelevant, political authorities would neither be in charge of risk management nor would they enjoy broad discretionary powers. In other words, in the field of EU risk regulation, political and administrative discretion is not self-standing. Rather, it derives from the overarching tenets of the precautionary principle and the need to take enhanced levels of protection and all relevant OLFs into due consideration.

Against this overall background, an analysis through the lens of socially acceptable risk approaches shows that the precautionary principle can be framed as an inner limit to the broad discretion of EU risk managers. Similar considerations apply to the case of EU legislators. Not only is the precautionary principle enshrined in the Treaties, it also underlies the institutional architecture of EU risk regulation and the delicate balance between functional and political-democratic legitimacy in this field.

C. The Precautionary Principle and EU Judicial Review

The case law of the Court has acknowledged the need for EU risk managers or EU legislators to take the precautionary principle into due consideration when adopting risk regulation measures.⁴⁹ This point is overall uncontroversial. The problem is, rather, how to *substantiate* compliance with the precautionary principle as an inner limit to the EU institutions' broad discretion in the field of risk regulation. The question then becomes how to judicially review compliance with the precautionary principle, when the latter is used as a sword. This specific question must be differently framed and addressed in respect of challenges to regulatory and legislative acts.⁵⁰

How is the Court to review compliance with the precautionary principle when the latter is used to attack regulatory acts which allegedly breach the precautionary principle, identify too low a threshold of acceptable risk, and do not ensure a sufficiently high level of protection? Several

⁴⁷Notably, in the United States. For an analysis, see *id.*

⁴⁸For this acknowledgment, see *Pfizer*, Case T-13/99 at para. 149.

⁴⁹For a finding that risk managers are bound to take precautionary action where precautionary risk management is warranted, see, for example, *France v. Commission*, Case T-257/07 at para. 66 (“[T]he precautionary principle is a general principle of EU law requiring the authorities in question, in the particular context of the exercise of the powers conferred on them . . . to take appropriate measures to prevent specific potential risks.”) (citing *Artegodan and Others*, Joined Cases T-74, 76, 83, 85, 132, 137 & 141/00 at para. 184).

⁵⁰On the difference between the two, see CJEU, Case C-583/11 P, *Inuit Tapiriit Kanatami*, ECLI:EU:C:2013:625 (Oct. 3, 2013).

difficulties arise in this respect, and a few preliminary considerations on the Court's standard of review in the field of EU risk regulation are necessary.

The Court has consistently acknowledged the broad discretion of EU institutions in cases involving complex technical evaluations.⁵¹ More specifically, as reiterated in *Fedesa*, “[discretion] does not apply exclusively to the nature and scope of the measures to be taken but also to some extent to the finding of the basic facts”⁵² Thus, in reviewing the exercise of such discretion, the Court “must confine itself to examining whether [an act] contains a manifest error or constitutes a misuse of power or whether the authority [clearly exceeded] the bounds of its discretion.”⁵³ Further, as highlighted since *Pfizer* and *Alpharma*, EU institutions enjoy a broad discretion when determining the level of risk deemed acceptable for society.⁵⁴ Thus, the Court has traditionally focused on and emphasised administrative discretion. The acknowledgment of the risk manager's broad discretion has consistently been the starting point in the Court's examination.

In cases where EU precautionary acts are challenged for being too restrictive, the broad administrative discretion of EU institutions implies that the Court can neither review the quality or soundness of the scientific evidence relied upon by the risk manager nor substitute its scientific evaluations for the ones of the risk manager.⁵⁵ A manifest error of assessment is all that can invalidate the relevant measures. While the notion of a manifest error has been differently framed and interpreted by the Court throughout its case law,⁵⁶ this test generally aims to and succeeds in safeguarding the EU risk manager's administrative discretion in choosing to enact precautionary measures. Ultimately, regardless of whether the Court focuses on mere administrative discretion or administrative discretion in precautionary risk management, precautionary measures are usually safeguarded.⁵⁷ These are cases where the precautionary principle directly or indirectly performs the function of a shield.⁵⁸

Under the different scenario where the precautionary principle is used as a sword, EU measures are challenged for not being protective enough. Framing the precautionary principle as an inner limit to the EU institutions' broad administrative discretion—as suggested in the previous section—comes with a set of legal implications. From this perspective, the manifest error of assessment test, as applicable to challenges involving acts which are deemed too restrictive, should not apply where the precautionary principle is used as a sword.

Ultimately, the notion of a manifest error is relevant in cases where the applicants—or referring courts—claim that EU risk regulatory measures are not informed by sound science or do not adhere to the positive results of a risk assessment. EU institutions are not under an obligation to enact evidence-based regulatory measures. In this sense, the Court's acknowledgment of the risk manager's broad discretion in precautionary risk management and the finding that only a manifest error of assessment can lead to the annulment of the relevant measures reflects the institutional architecture of EU risk regulation. A manifest error is all that can invalidate an EU act where EU institutions have exercised their discretion to enact precautionary measures. Conversely, if the precautionary principle is framed as an inner limit to the EU institutions' broad discretion, the relevant question in challenges against insufficiently protective acts should *not* be

⁵¹See CJEU, Case C-138/79, *Roquette v. Council*, ECLI:EU:C:1980:249 (Oct. 29, 1980), para. 25.

⁵²Opinion of Advocate General Mischo at para 12, Case C-331/88, *The Queen v. Minister of Agriculture, Fisheries and Food and Secretary of State for Health, ex parte: Fedesa and others* (Nov. 30, 1990) [hereafter *Fedesa*]. See also *Pfizer*, Case T-13/99 at para. 168; *Alpharma*, Case T-70/99 at para. 179.

⁵³*Fedesa*, Case C-331/88 at para 12. See also *Pfizer*, Case T-13/99 at para. 166; *Alpharma*, Case T-70/99 at para. 177.

⁵⁴See *Pfizer*, Case T-13/99 at para. 167; *Alpharma*, Case T-70/99 at para. 178.

⁵⁵See, e.g., *Pfizer*, Case T-13/99 at para.169; *Alpharma*, Case T-70/99 at para. 180, (“[T]he judicature is not entitled to substitute its assessment of the facts for that of [EU] institutions.”).

⁵⁶Leonelli, *Acknowledging the Centrality of the Precautionary Principle in Judicial Review of EU Risk Regulation: Why it Matters*, *supra* note 18.

⁵⁷*Id.*

⁵⁸For use of the terminology of the precautionary principle as a “shield” or a “sword,” see Scott & Vos, *supra* note 3.

whether EU institutions have incurred a manifest error. Rather, the question becomes whether EU risk managers have complied with the overarching tenets of the precautionary principle. As the next sections show, the Court has implicitly recognized the difference between judicial review of acts which are deemed too restrictive, on the one hand, and acts deemed insufficiently protective, on the other hand. While in the latter case the Court has sometimes resorted to the manifest error test,⁵⁹ it has ultimately applied it differently.

Yet, the relevance of the notion of administrative discretion and its relationship to precautionary risk management resurfaces in judicial review of compliance with the precautionary principle. The main problem in cases where the precautionary principle is used as a sword lies in striking a fair balance between judicial review of *compliance* with the precautionary principle, on the one hand, and the acknowledgment of the EU risk manager's *discretion in complying* with the precautionary principle, on the other hand. This dichotomy is encapsulated in the Court's finding in *Artegodan* that, in the face of scientific uncertainty:

[W]hether to have recourse to the precautionary principle depends as a general rule on the level of protection chosen by the competent authority in the exercise of its discretion That choice must, however, comply with the principle that the protection of public health, safety and the environment is to take precedence over economic interests⁶⁰

As already explained, the precautionary principle mandates that precautionary measures should be enacted when, in the face of inconclusive, insufficient, or incomplete scientific evidence, uncertain risks might not meet the intended level of protection. This definition entails the exercise of discretion in at least three respects: in the evaluation of the entity and extent of *scientific uncertainty* triggering application of the principle; in the identification of the *intended level of protection* in the field; and in the final determination that, in the face of scientific uncertainty and having regard to the intended level of protection, a *specific risk is too high* to meet the threshold of acceptable risk. In this context, how can the Court fruitfully review whether scientific uncertainty warrants the enactment of precautionary measures, whether the intended level of protection is high enough, and whether the resulting threshold of acceptable risk is too low? Ultimately, this calls into question the possibility to set the boundaries of discretion in compliance with the precautionary principle, establishing the specific conditions under which these boundaries are overstepped. Indeed, judicial review of compliance with the precautionary principle would otherwise become a slippery slope; in the face of persisting scientific uncertainty, any measure short of a ban or stringent restriction could in abstract be challenged for allowing risks which are perceived as socially unacceptable.

Further difficulties in the use of the precautionary principle as a sword arise with respect to the burden of proof. Challenging a precautionary risk management measure for being too restrictive, on the grounds of alleged manifest errors of assessment or a misapplication of the precautionary principle, might seem hard. Yet, in these cases, the applicants usually lament the application of prudential methods or models, point to the positive results of risk assessment, and focus on the absence of conclusive scientific proof of hazards or risks.⁶¹ None of this happens where a measure is challenged for not being precautionary enough.

In this case the applicants will point to uncertainties emerging from the single stages of risk assessment, different studies referring to persisting scientific uncertainty, the insufficiency or incompleteness of relevant data, and the failure to conduct further assessments to dispel uncertainty. In the best case scenario, they might be able to adduce diverging evidence on the

⁵⁹See *infra*, Sections D and F.

⁶⁰*Artegodan and Others*, Joined Cases T-74, 76, 83, 85, 132, 137 & 141/00 at para. 184.

⁶¹Leonelli, *Acknowledging the Centrality of the Precautionary Principle in Judicial Review of EU Risk Regulation: Why it Matters*, *supra* note 18.

characterisation of the relevant hazards or risks. In any case, in evidentiary terms, using the precautionary principle as a sword is without a doubt more difficult than challenging a precautionary act for being too restrictive. This is inherent to the sound science—what has been conclusively proven and established—versus uncertainty—what is unknown—dichotomy. This point triggers a set of further questions. How pervasive must scientific uncertainty be, how likely and how high the relevant risks, and how significant the potential adverse effects, for the Court to find that the risk manager has not complied with the precautionary principle? What is the requisite standard of proof? As the next section illustrates, the Court has given some indications on both issues, by indirectly setting the boundaries of discretion in compliance with the precautionary principle and providing some insights on the requisite standard of proof. These indications emerge from two cases: *Paraquat*, which is the only successful action where the precautionary principle has been used as a sword, and *France v. Commission*.

Challenges to legislative acts trigger a different set of considerations. Different evaluations as to whether legislative frameworks and regulatory arrangements are *robust enough* to ensure that a comprehensive risk assessment is conducted, uncertainties are dispelled, and the risk manager is in a position to enact precautionary measures are at stake. The three cases analyzed in the following sections involved a request for a preliminary ruling on the validity of legislative acts; in all cases, the referring court raised doubts as to the compatibility of legislative provisions with the precautionary principle, using the latter as a sword. These cases call into question the institutional architecture and regulatory arrangements underlying the relevant legislative frameworks. These regulatory arrangements, in turn, are based on specific legislative choices as to the preconditions for conducting a risk assessment,⁶² the boundaries and scope of risk assessment,⁶³ the scope of application of the legislative acts,⁶⁴ and the distribution of regulatory authority among EU institutions and Member States.⁶⁵

Clearly, judicial review of compliance with the precautionary principle comes with several difficulties in the case of legislative acts. First, the referring courts have called into doubt whether the *procedural* governance arrangements underpinning the legislative acts would enable the relevant institutions to take into due consideration the precautionary principle and ensure a high level of protection in *substantive* terms. The questions of the national courts boil down to whether the regulatory arrangements in place are sufficient for a *thorough risk assessment* to be conducted and *scientific uncertainty* to be dispelled as much as possible.⁶⁶ In this sense, the national courts' questions on compliance with the precautionary principle suggest that the regulatory arrangements are inadequate for the purpose of informing the technical-scientific knowledge of the risk manager and enabling him to set the threshold of acceptable risk, taking the precautionary principle into account. These elements can be very hard to review.

Second, it can be difficult to draw a line between questions of regulation and institutional architecture, on the one hand, and regulatory implementation, on the other hand. Regulatory arrangements can be perfectly fit, in abstract terms, to ensure that a comprehensive risk assessment is conducted and all relevant evidence gathered at one or more institutional levels. Yet regulatory practice at the implementation stage might not achieve this goal, undermining precautionary risk management. The two dimensions should not be confused. Judicial review by the Court can only target the regulatory arrangements underlying the institutional framework.

⁶²See *Monsanto Italia*, Case C-236/01.

⁶³See *Monsanto Italia*, Case C-236/01; *Blaise*, Case C-616/17.

⁶⁴*Confédération Paysanne*, Case C-528/16.

⁶⁵*Blaise*, Case C-616/17.

⁶⁶*Monsanto Italia*, Case C-236/01, involved an evaluation of comparative—as opposed to risk—assessments. *Confédération Paysanne*, Case C-528/16, entailed an evaluation of the scope of application of the Deliberate Release Directive, with all connected regulatory obligations. Finally, *Blaise*, Case C-616/17, involved an evaluation of the governance arrangements in place for risk assessment of pesticidal active substances and plant protection products—pesticides.

Finally, it is worth stressing that legislative acts, adopted under the legislative procedures, enjoy a high degree of democratic legitimacy. In her Opinion in *Inuit*, Advocate General Kokott justified the limits to direct access to the CJEU when legislative—rather than regulatory—acts are at stake on the grounds of the former’s democratic legitimacy.⁶⁷ Arguably, to some extent, the difference between legislative and regulatory acts is also reflected in the different intensity of the Court’s review.

Against this overall background, the following sections turn to an analysis of cases involving regulatory and legislative acts respectively. Section D starts by providing an overview of *Paraquat* and *France v. Commission*, the only cases involving insufficiently protective regulatory acts where the Court has examined the issue of compliance with the precautionary principle.⁶⁸ Sections E and F examine challenges to legislative acts where the precautionary principle has been used as a sword. Section E analyzes *Monsanto Italia* and *Confédération Paysanne*, while Section F engages in a more detailed examination of the highly complex matters at stake in *Blaise*.

D. Judicial Review of EU Regulatory Acts: The “Quantitative Threshold” Approach

In *Paraquat*, Sweden challenged the approval of a pesticidal active substance by means of its inclusion in Annex I to Directive 91/414—the predecessor of the PPP Regulation. Scientific uncertainty persisted as to the extent of the risks posed by exposure to paraquat, including the possibility of adverse effects such as limited capacity to absorb oxygen, skin cancer, and development of Parkinson’s Disease.⁶⁹ Further, this active substance is acknowledged to cause fatal effects on birds and hares. The Scientific Committee on Plants and the Commission, basing their decision on field exposure studies, took the view that paraquat would not pose any significant health risks for operators as long as it was used as recommended under prescribed good working practices. As to the adverse effects on birds and hares, the Scientific Committee and the Commission argued that further information on realistic exposure would be needed for the purposes of a definitive risk assessment, but risks would be acceptable as long as risk mitigation measures were in place.⁷⁰

Sweden raised two pleas in law. In the first plea, it alleged several infringements of the relevant procedures.⁷¹ In the second plea, it lamented an infringement of Article 5 of the 1991 Directive, a breach of the precautionary principle, and a breach of the principle that a high level of public health and environmental protection must be ensured.⁷² Upon an analysis of the uncertain risks to public health posed by the use of paraquat, Sweden pointed out that the models applied and the evidence from field studies showed that the exposure of users to paraquat would exceed the Acceptable Operator Exposure Level (AOEL) provided for under Article 5 and Annex VI of

⁶⁷Opinion of Advocate General Kokott at para. 38, Case C-583/11 P, *Inuit Tapiriit Kanatami* (Jan. 17, 2013).

⁶⁸It is only in a few instances that challenges against EU regulatory acts deemed insufficiently protective have been brought on the basis of the precautionary principle. In all cases but *Paraquat*, Case T-229/04, the relevant acts have been annulled for breaches of procedural provisions which are unrelated to the application of the precautionary principle. See CJEU, Case C-393/01, *France v. Commission*, ECLI:EU:C:2003:307 (May 22, 2003); CJEU, Case C-14/06, *Parliament and Denmark v. Commission*, ECLI:EU:C:2008:176 (Apr. 1, 2008); CJEU, Case T-240/10, *Hungary v. Commission*, ECLI:EU:T:2013:645 (Dec. 13, 2013). In one case, *France v. Commission*, the action and appeal were unsuccessful. Overall, it is unsurprising to see how few these actions are; it is equally unsurprising that they have all been brought by Member States. Owing to the standing criteria of TFEU Article 263(4), environmental NGOs or societal stakeholders willing to use the precautionary principle as a sword in challenges against regulatory acts face considerable obstacles in direct access to the CJEU. For an overview of these obstacles, see Giulia Claudia Leonelli, *A Threefold Blow to Environmental Public Interest Litigation: The Urgent Need to Reform the Aarhus Regulation*, 45 EUR. L. REV. 324 (2020).

⁶⁹*Paraquat*, Case T-229/04 at paras. 59, 60, 65–68.

⁷⁰*Id.* at para. 42.

⁷¹This plea in law was also upheld.

⁷²*Paraquat*, Case T-229/04 at para. 54.

the Directive.⁷³ According to the Annex, authorizations could not be granted if the extent of operator exposure in handling and using the plant protection product under the proposed conditions of use, including doses and application methods, exceeded the AOEL.

Sweden supported a precautionary interpretation of Article 5 and Annex VI, emphasizing that “a substance may not be included in Annex I until it has been proven *beyond reasonable doubt* that a product containing that active substance can be used *with complete safety* in at least one representative type of use.”⁷⁴ On these grounds, it submitted that the relevant scientific evidence was insufficient to support the conclusion that paraquat would not pose significant risks to public health, and that the legal provisions of the 1991 Directive, the precautionary principle, and the principle of a high level of health protection had been breached.⁷⁵ With regard to the adverse effects on birds and hares, Sweden complained that the scientific dossier contained insufficient evidence on exposure to prove that the environmental risks of paraquat would be acceptable. The Commission, with respect to both claims, argued that all relevant scientific evidence had been taken into due account and that the risks posed by paraquat would be acceptable, as long as risk mitigation measures were complied with.

The Court found that Article 5 of the Directive, “interpreted in combination with the precautionary principle, [implies that] in the domain of human health the existence of *solid evidence* which, while not resolving scientific uncertainty, may reasonably raise *doubts as to the safety* of a substance, justifies, in principle, the refusal to include that substance in Annex I.”⁷⁶ Again by reference to the precautionary principle, it noted that “before including a substance in Annex I . . . it must be established *beyond a reasonable doubt* that the restrictions on the use of the substance involved make it possible to ensure that use of that substance will be in accordance with the requirements”⁷⁷

Against this backdrop, it went on to assess whether the evidence adduced by Sweden could raise doubts as to the safety of paraquat, in accordance with the criteria enshrined in Article 5 and Annex VI. The Court found that the Guatemalan and French studies relied upon by Sweden constituted solid evidence attesting to a level of exposure higher than the AOEL, and raised doubts as to the safety of paraquat for operators.⁷⁸ As to the complaints alleging that scientific evidence on adverse effects on birds and hares was insufficient to establish that the risks were acceptable,⁷⁹ again, the Court maintained that, in accordance with the

⁷³See *id.* at para. 70:

[Sweden] claims, first of all, that the models show without ambiguity that the exposure of users to paraquat exceeds the AOEL. It states that, according to the two models used to calculate the exposure of professional users to paraquat, taking account of the presence or absence of personal protective equipment and different ways of using the substance (knapsack or tractor-mounted sprays) the exposure of such users exceeds by 4 to 100 times the threshold laid down. The values are 20 to 100 times higher than the AOEL for workers using a knapsack but not wearing protective clothing whereas they are 60 times higher than the AOEL where gloves are used when handling or spraying the substance. Finally, even with gloves, breathing equipment, overalls, wide-brimmed hats and solid shoes, the level of exposure is above the AOEL.

See also *id.* at para. 71, on field studies.

⁷⁴*Id.* at paras. 140, 141 (emphasis added).

⁷⁵*Id.* at paras. 139–59.

⁷⁶*Id.* at para. 161 (emphasis added).

⁷⁷*Id.* at para. 170.

⁷⁸*Id.* at paras. 172–92.

⁷⁹See *id.* paras. 192–215 (emphasis added):

[Sweden] claims, in substance, that point C 2.5.2.1 of Annex VI indicates that, where there is a possibility of birds or other non-target terrestrial vertebrates being exposed, a special upper limit and a margin of safety—in accordance with which the long-term toxicity/exposure ratio is to be 5 or above—must be applied. However, the studies on which the Commission based its assessment of paraquat show that the ratio in question was only 2. It adds that the Commission has not shown that there is a use for paraquat in which the risk of exposure for ground-nesting birds would be acceptable. It follows that the Commission cannot conclude, on the basis of the existing dossier, that there are no unacceptable risks.

precautionary principle, the existence of solid evidence which may reasonably raise doubts as to the safety of a substance justifies its non-inclusion.⁸⁰ The Court found that, under Annex VI, no authorizations should be granted where the long-term toxicity and exposure ratio is below five, unless an appropriate risk assessment showed no unacceptable impact due to risk mitigation measures.⁸¹ However, as argued by Sweden, the scientific evidence relied upon by the Commission was insufficient for the purposes of such risk assessment.⁸² On these grounds, both branches—public health and environmental risks—of the pleas in law alleging infringement of the 1991 Directive, breach of the precautionary principle, and breach of a high level of protection were accepted.

Paraquat sheds some light on the threshold of risk which will trigger a finding that the risk manager has failed to comply with the precautionary principle. In this case, scientific evidence pointed to severe potential adverse effects of paraquat on human health. Further, lethal or quasi-lethal effects on animals had been established. Scientific uncertainty and disagreements as to the adequacy and effectiveness of risk mitigation measures were also very high. In the case of public health, some models and field studies testified that exposure would still considerably exceed the AOEL; in the case of animal health, the data was insufficient to establish realistic exposure. Therefore, the relevant uncertain risks were significant. Further, the Court's reasoning and interpretation of the Directive in light of the precautionary principle was supported by the express AOEL and toxicity and exposure ratio requirements of Annex VI. In this sense, the Commission had failed to meet its burden of proof; it had failed to establish that the authorization of paraquat, in the face of persisting uncertainty, would comply with the explicit requirements of the Directive.

What can be inferred from *Paraquat* is that the threshold of risk triggering a breach of the precautionary principle is a very high one. Scientific uncertainty, including the insufficiency and incompleteness of available scientific evidence, must be very high. The relevant risks, as resulting from the specific hazards and potential exposure, must also be very high. As a consequence, it will be highly unlikely, if not implausible, that the risk manager has pursued a high level of protection. On these grounds, the Court will be able to infer that the threshold of acceptable risk is too low for compliance with the precautionary principle.

In this sense, the threshold for a judicial finding that the precautionary principle has been breached is quantitative, rather than qualitative. Symmetrically, the burden of proof is very high on the applicants. The latter will have to adduce evidence that the relevant risks are very high, which could be established by reference to high levels of uncertainty, high hazards, and high exposures, or significant divergencies in data obtained through the application of different models.

This quantitative approach blurs the boundaries between review of compliance with the precautionary principle, on the one hand, and manifest errors of assessment, on the other hand. Admittedly, more than a mere breach of the precautionary principle was at stake in *Paraquat*; the Commission had failed to make a convincing case that the approval of the active substance complied with a set of express legislative requirements. In this sense, it might as well have manifestly erred in its evaluation that the use of paraquat complied with the relevant legislative provisions. Nonetheless, it is still worth stressing that a deferential review of the Commission's broad discretion might have resulted in a finding that the Commission had not incurred a manifest error of assessment.

All in all, was the decision in *Paraquat* about manifest errors of assessment or a breach of the precautionary principle? Is it reasonable to suggest that the decision in *Paraquat* would have looked the same, if considerable uncertainties persisted but the legislative requirements—for example the AOEL—had been somewhat met? Both questions are rather difficult to answer. Undoubtedly, the precautionary principle played a key role in the Court's interpretation. On these

⁸⁰*Id.* at para. 224.

⁸¹*Id.* at para. 226.

⁸²*Id.* at para. 233–52.

grounds, and considering the high risks identified in this case, we may infer that even under a scenario where the AOEL had been somewhat met, the Court would have taken the same quantitative threshold perspective and annulled the act. In this sense, the Court's decision does not rest on the identification of a mere manifest error of assessment; compliance with the precautionary principle was at stake. What is certain, however, is that judicial review of compliance with the precautionary principle will not catch measures which are perceived as insufficiently protective in qualitative terms.

This is perfectly illustrated by *France v. Commission*, where the typical precautionary principle dilemma was at stake. How safe is safe,⁸³ and when is safe safe enough?⁸⁴ How should the boundaries of precautionary levels of protection be outlined, and how should the threshold of acceptable risk be reviewed? In this case, France challenged a 2008 Commission Regulation authorizing less restrictive measures of surveillance and eradication for ovine and caprine flocks in the context of prevention and control of transmissible spongiform encephalopathies (TSEs). By its sole plea in law, France alleged a breach of the precautionary principle in the context of both risk assessment and risk management.⁸⁵ This was substantiated by a plurality of complaints surrounding the Commission's disregard or misinterpretation of persisting uncertainty on the transmissibility of TSEs to humans, the reliability of the tests adopted, the alleged biased use of the EFSA's Opinion, and the failure to assess the increase in risk resulting from the adoption of the less restrictive measures. In other words, France argued that in light of persisting uncertainties, the risks associated with the relaxation of the measures were too high to be acceptable and did not meet the requirement of a high level of protection.

The Court thoroughly analyzed whether all relevant assessments had been conducted, whether the Commission had taken their results into due consideration, and, importantly, the entity and extent of persisting uncertainties and the level of any relevant risks to public health. At paragraph 86, the Court mentioned the manifest error of assessment test, arguing that the evidence adduced by France would have to be sufficient "to make the factual assessments used in the act implausible."⁸⁶ Nonetheless, in fact, the Court's review focused on the boundaries of scientific uncertainty and the level of risk arising from the new measures, confirming the quantitative threshold approach outline above. Throughout the judgment, the Court explicitly and repeatedly referred to the finding that the risks in this field were "low,"⁸⁷ "very low,"⁸⁸ or "extremely low."⁸⁹ Against this backdrop, the Court concluded that the Commission was entitled to relax the pre-existing risk management measures without incurring a manifest error of assessment; in other words, uncertain risks were low enough to ensure that the level of protection would be sufficiently high.

This case demonstrates that by following a quantitative threshold approach, the Court will not engage with normative disagreements surrounding qualitative evaluations of risk. Namely, the determination of whether uncertain risks are acceptable and whether the decision to run these risks meets the goal of enhanced and precautionary levels of protection. As explained above, uncertainties can arise in a plurality of contexts. Further, and as occurred in *France v. Commission*, even the same science can be interpreted differently and lead to different inferences and conclusions as to whether uncertain risks are acceptable. This is the slippery slope of the precautionary principle; normative and political disagreements over the identification of the intended level of protection and threshold of acceptable risk will often persist. Arguably, this qualitative aspect of controversy goes to the heart of the precautionary principle, reaching its authentic understanding and value. The Court, however, will not engage with this dimension.

⁸³Nicolas de Sadeleer, *The Precautionary Principle in EC Health and Environmental Law*, 12 EUR. L.J. 139, 147 (2006).

⁸⁴Lee, *supra* note 7, at 244.

⁸⁵*France v. Commission*, Case T-257/07 at para. 90.

⁸⁶*Id.* at para. 86.

⁸⁷See *id.* at paras. 104, 109, 137, 149.

⁸⁸See *id.* at paras. 107, 150, 151, 163–71, 219, 261.

⁸⁹See *id.* at paras. 96, 98, 100, 108, 109, 150, 151, 155, 159, 229, 230, 240, 251.

This is legally tenable and appropriate in light of the nature of the precautionary principle. By implicitly resorting to a quantitative threshold approach, the Court has ultimately set the boundaries for judicial review of compliance with the precautionary principle, as opposed to the exercise of discretion in complying with the precautionary principle. The quantitative threshold approach enables review of compliance with the precautionary principle. Qualitative disagreements, by contrast, will not be caught, as discretion in complying with the precautionary principle will be safeguarded.

In legal terms, this strikes a fair balance between the two dimensions. In this sense, however, the inner limits to the risk manager's exercise of his broad administrative discretion are quite thin. Qualitative disagreements on the threshold of acceptable risk will have to be solved in the political arena. As clearly emerges from the Court's case law, "the level of risk deemed unacceptable for society in a specific case results from a political choice which lies with the competent authority and not with the Court."⁹⁰ Further, "... policy concerns ... must be dealt with in political fora. It is not for this or any other court to determine proper national or [EU] environmental policy."⁹¹

E. Judicial Review of EU Legislative Acts (I): The Nature and Scope of Risk Assessment

In *Monsanto Italia*, the Court was called upon to deliver a ruling on the interpretation and validity of the simplified procedure for the placing on the market of genetically engineered food and feed ingredients (GMOs), as provided for under the old system of Regulation 258/97. Pursuant to the Annex to Recommendation 97/618, where a novel (in the case at hand, genetically engineered) food was deemed to be substantially equivalent to its conventional counterpart, the former would not go through an encompassing risk assessment. Thus, no toxicological data and no further testing would be needed.⁹² The simplified notification procedure would then apply.

At a general level, regulatory approaches to the governance of genetically engineered organisms may either draw on product or process-based models. Under the former model, the process of genetic engineering is presumed not to pose inherent risks; genetically engineered organisms, as a class, are presumed to be substantially equivalent to their conventional counterparts, unless they have specific characteristics or properties. Under the precautionary process-based model, by contrast, all genetically engineered organisms are the object of a thorough risk assessment. Use of the simplified procedure, on the basis of a mere comparative assessment of substantial equivalence, clearly drew on a product-based approach. Many Member States had expressed concerns about the use of the simplified procedure, pointing to the uncertain risks posed by genetically engineered food varieties.⁹³ The Commission also entertained some doubts as to its adequacy.⁹⁴ The new 2001 to 2003 framework, indeed, draws on a process-based model.

In those circumstances, the referring court raised several questions surrounding the interpretation of the simplified procedure, the Member States' power to resort to the safeguard clause of

⁹⁰*Id.* at para. 214.

⁹¹Opinion of Advocate General Sharpston at para. 145, Joined Cases C-439 & 454/05, *Land Oberösterreich and Austria v. Commission* (15 May 2007).

⁹²*Monsanto Italia*, Case C-236/01 at para. 14. For a commentary on this case, see also Dabrowska, *GM Foods, Risk, Precaution and the Internal Market: Did Both Sides Win the Day in the Recent Judgment of the Court of Justice?*, 5 GERMAN L. J. 151 (2004).

⁹³*Monsanto Italia*, Case C-236/01 at para. 37.

⁹⁴*Id.* at para. 65.

Following ... critical reassessment, the Commission arrived at the conclusion that, given the current state of scientific research, it appears that foods containing transgenic protein may, in principle, no longer be considered substantially equivalent to existing foods within the meaning of the first subparagraph of Article 3(4) of Regulation No 258/97 unless a full assessment of their characteristics makes it possible to be certain beyond any reasonable doubt that all the conditions laid down in that provision are satisfied.

Article 12(1) of the 1997 Regulation, and the validity of the simplified procedure in light of the precautionary principle.⁹⁵ All in all, the referring court expressed doubts on the assessments conducted under the simplified procedure, implying that the latter would not enable risk managers to collect sufficient information on the uncertain risks posed by genetically engineered foods. On these grounds, it suggested that the regulatory arrangements underlying the streamlined simplified procedure neither complied with the precautionary principle nor ensured a high level of protection.

In its analysis, the Court first argued that comparative assessments aim to identify potential risks on the basis of the differences observed between genetically engineered organisms and conventional counterparts. It then went on to argue that, where differences and potential risks have been identified, a more comprehensive assessment would be required. On these grounds, it suggested that the simplified procedure did not undermine the precautionary principle, given that the identification of differences and potential risks would trigger a risk assessment.⁹⁶ Arguably, this part of the ruling misses the whole point of the national court's question. In the face of persisting uncertainty on the effects of genetic engineering, a mere comparative assessment is—as such—insufficient to detect potential risks; rather, a more thorough risk assessment should be conducted for each and every variety. This is what the national court meant by inquiring into compliance with the precautionary principle.

Second, the Court noted that the recognition of substantial equivalence might have been subsequently reassessed at EU or national level.⁹⁷ Finally, it found that the safeguard clause enshrined in Article 12 of the Regulation gave express recognition to the precautionary principle.⁹⁸ Against this overall backdrop, it concluded that the provisions relating to the simplified procedure complied with the precautionary principle.

This case shows the Court's unequivocal reluctance to engage in a thorough analysis of the regulatory architecture of the 1997 Regulation. The Court refrained from inquiring into the robustness of the relevant arrangements and from analyzing whether—in conditions of scientific uncertainty—comparative assessments under the simplified procedure would in fact provide the risk manager with all necessary scientific evidence, enabling him to take a precautionary approach to risk management. Ultimately, in this case the Court refrained from taking a position in the scientifically and politically controversial field of genetically engineered organisms, leaving it to the EU legislator to overhaul the legislative framework. Though this is politically understandable, it is fair to suggest that the Court's legal analysis of compliance with the precautionary principle was highly deferential.

This did not occur in *Confédération Paysanne*, where the Court was more proactive in its legal examination. This request for a preliminary ruling concerned the interpretation and validity of the mutagenesis exemption under the 2001 Deliberate Release Directive. This Directive regulates the environmental release of genetically engineered crops for field test or cultivation purposes, as well as the placing on the market of genetically engineered seeds and products other than food and feed. The term “mutagenesis” encompasses a range of genetic engineering techniques which have considerably evolved in the twenty years since the enactment of the 2001 Directive.

Under Article 2(2) of the Directive, genetic modification occurs at least through the use of the techniques listed in Annex I(A), part 1; the techniques listed in Annex I(A), part 2, on the other hand, are not considered to result in genetic modification. Mutagenesis is listed in neither part of the Annex. Pursuant to Article 3(1), the techniques of genetic modification listed in Annex I(B) do not fall within the scope of application of the 2001 Directive. Mutagenesis is included in this Annex. The applicant in the national proceedings lamented that organisms obtained through

⁹⁵*Id.* at para. 48.

⁹⁶*Id.* at para. 129.

⁹⁷*Id.* at para. 138.

⁹⁸*Id.* at para. 133.

new mutagenesis techniques, unknown back in 2001, were exempted from the obligations laid down in the French environmental code, which implements the 2001 Directive. Most importantly, such organisms pose uncertain health and environmental risks which are comparable to the ones posed by traditional GMOs, created through the application of transgenesis techniques.

By its first question, the referring court asked whether organisms created through “new” mutagenesis techniques constituted genetically modified organisms within the meaning of Article 2. Further, and crucially, it inquired whether Articles 2 and 3 as well as Annexes I(A) and I(B) to the Directive should be interpreted as meaning that they exempt from the Directive’s environmental risk assessment and traceability obligations all organisms obtained through mutagenesis, or only organisms obtained through mutagenesis techniques known at the time the Directive was adopted. Regarding the question of whether the Court should have confirmed the general application of the mutagenesis exemption, the referring court inquired about these provisions’ compatibility with the precautionary principle.⁹⁹

The applicants in the national case and the French government expressly suggested an interpretation of the mutagenesis exemption in light of Recital (17) of the Directive and the precautionary principle.¹⁰⁰ According to Recital (17), the 2001 Directive “should not apply to organisms obtained through certain techniques of genetic modification which have *conventionally* been used in a number of applications and have a *long safety record*.”¹⁰¹ The precautionary principle, as applicable to review of legislative acts and as already explained, postulates that scientific uncertainty should be dispelled as much as possible and that the risk manager should have all relevant scientific evidence available, with a view to establishing whether uncertain risks meet the intended level of protection. Referring to the legal underpinning of Recital (17) and the overarching tenets of the precautionary principle, the applicants and France thus argued that the mutagenesis exemption should *not* apply to organisms obtained through new mutagenesis techniques.

Advocate General Bobek took a diametrically opposite view. With respect to the first question, he found that the text, historical context, and internal logic of the 2001 Directive did not support the proposition that new mutagenesis techniques should not be exempted.¹⁰² On these grounds, he concluded that “the precautionary principle cannot lead . . . to rewriting the provisions of the legal text . . . contra legem,”¹⁰³ adding that “it is certainly not the role of this Court to start judicially rewriting definitions and categories.”¹⁰⁴

Further, in his assessment of the potential invalidity of the mutagenesis exemption vis-à-vis the precautionary principle,¹⁰⁵ he also found that no legal elements lent support to the claim of a breach of the precautionary principle. In this respect, he argued, no grounds could be identified to substantiate the argument that absence of environmental risk assessment and traceability obligations violated the precautionary principle.¹⁰⁶ The Opinion underlines that scientific knowledge as to the concrete risks posed by new mutagenesis techniques is very limited. However, reliance on the precautionary principle presupposes that a risk cannot be purely hypothetical, but scientifically verified. On this basis, the Advocate General claimed that the precautionary principle could not apply.¹⁰⁷ Arguably, this is a circular argument. The Opinion suggests that the precautionary principle is not at stake insofar as the uncertain risks posed by new mutagenesis techniques have

⁹⁹*Confédération Paysanne*, Case C-528/16 at para. 25.

¹⁰⁰See the reference to this point in Opinion of Advocate General Bobek at para. 87, Case C-528/16, *Confédération Paysanne v. Premier Ministre* (Jan. 18, 2018).

¹⁰¹Deliberate Release Directive, recital (17) (emphasis added).

¹⁰²Opinion of Advocate General Bobek, *supra* note 100, at para. 91. For the A.G.’s analysis and textual interpretation of the Directive, see in particular paras. 80–85.

¹⁰³*Confédération Paysanne*, Case C-528/16 at para. 103.

¹⁰⁴See *id.* at paras. 89, 104.

¹⁰⁵For the rather restrictive interpretation of the precautionary principle in the Opinion in this Case, see *id.* at para. 48–54.

¹⁰⁶*Id.* at paras. 130, 143.

¹⁰⁷*Id.* at paras. 146, 147.

not been identified. Yet, the applicants lamented a breach of the precautionary principle in that the absence of comprehensive risk assessments does not allow for the identification of any such risks.¹⁰⁸

In its ruling, the Court engaged in a teleological interpretation of the mutagenesis exemption in light of Recital (17) and the precautionary principle. Upon remarking that new mutagenesis techniques pose risks which are comparable to those posed by traditional genetic modification,¹⁰⁹ it went on to emphasize the role and value of the precautionary principle in the context of the 2001 Directive.¹¹⁰ It thus found that a restrictive interpretation of the mutagenesis exemption would fail to take into consideration heed the intention of the legislator, as apparent from Recital (17), and would “compromise the objective of protection pursued by the Directive and . . . fail to respect the precautionary principle, which [the Directive] seeks to implement.”¹¹¹ On these grounds, it did not need to address the question on the validity of the mutagenesis exemption.

This case perfectly exemplifies the clash between judicial restraint, as apparent from the Opinion of the Advocate General, and an interpretation of EU legislative acts in light of the precautionary principle. The Court’s ruling has been a most welcome addition to the debate in this field. Yet, it is worth stressing that, unlike in *Monsanto Italia*, the Court had rather strong legal elements to underpin its own teleological interpretation. From this perspective, the Court’s ruling offers an example of balanced and legally informed interpretation in the context of judicial review of compliance with the precautionary principle; it should neither be defined as a case of judicial rewriting, nor as a case of judicial activism. Arguments in favor of judicial restraint in cases like *Confédération Paysanne*, by contrast, appear to draw on a reluctance to acknowledge the status and role of the precautionary principle as a general principle of EU law enshrined in the Treaties and in legislation.

F. Judicial Review of EU Legislative Acts (II): *Blaise* and The Question of Regulatory Implementation

The Opinion of the Advocate General and the Judgment of the Court in *Blaise* provide a rather concise overview of the institutional architecture underlying the Plant Protection Product (PPP) Regulation.¹¹² For this reason, a more thorough examination of the relevant governance arrangements is necessary to fully grasp the rationale of the specific questions referred by the national court and the issues surrounding the implementation of the Regulation.

The scope of application of the PPP Regulation encompasses active substances, safeners, synergists, co-formulants, adjuvants, and plant protection products (PPPs).¹¹³ The Regulation does not provide a legal definition of “active substances.” Active substances, however, are scientifically acknowledged to be the main active constituent(s) with pesticidal properties in a PPP, which is commonly known as a pesticide. As clarified in the PPP Regulation and in relevant implementing acts, active substances can be produced by different manufacturing processes, leading to differences in specifications, metabolites, degradation products, and impurities; these differences might have safety implications.¹¹⁴ Safeners are substances or preparations which are added to

¹⁰⁸In other words, it is impossible to establish and prove any potential adverse effects if a risk has not been assessed in the first place.

¹⁰⁹*Confédération Paysanne*, Case C-528/16 at para. 48.

¹¹⁰*Id.* at paras. 49, 50.

¹¹¹*Id.* at Para. 53.

¹¹²PPP Regulation, *supra* note 12.

¹¹³*Id.* at art. 3.

¹¹⁴See PPP Regulation, *supra* note 12, Recital (27), arts. 3(32), (33) for definitions of “metabolites” and “impurities.” See also Commission Regulation 546/2011 of 10 June 2011 Implementing Regulation of the European Parliament and of the Council 1107/2009 as regards Uniform Principles for Evaluation and Authorization of Plant Protection Products, 2011 O.J. (L 155); Commission Regulation 283/2013 of 1 March 2013 setting out the Data Requirements for Active Substances, in Accordance

eliminate or reduce the phytotoxic effects of a PPP.¹¹⁵ Synergists have limited pesticidal properties if any, but can give enhanced activity to the active substance(s) contained in a PPP.¹¹⁶ Finally, *co-formulants* are used in a PPP or an adjuvant for purposes different from the ones of a safener or synergist,¹¹⁷ whereas adjuvants are substances or preparations consisting of one or more co-formulants and which are intended to be mixed with a PPP, with a view to enhancing its effectiveness or its pesticidal properties.¹¹⁸

PPPs are made up of active substance(s) and a range of co-constituents, which may include safeners, synergists, and other co-formulants. They can be formulated in many different ways, as the specific co-constituents or their relative quantities in the final product may vary. Article 2(1) provides a list of their potential aims and uses, including protecting plants or plant products against harmful organisms, influencing the life processes of plants, preserving plant products, destroying undesired plants or parts of plants, and preventing undesired growth of plants. It is estimated that around 500 different PPPs are authorized and marketed across the EU.¹¹⁹

Article 27 provides for the adoption of an EU negative list of co-formulants which shall not be accepted for inclusion in a PPP. Co-formulants shall be banned at EU level where their use—consequent on application consistent with good plant protection practice and having regard to realistic conditions of use—has harmful effects on human and animal health or unacceptable effects on plants, products, or the environment. The same applies where their residues, under the same conditions, have harmful effects on human and animal health or groundwater or unacceptable effects on the environment.¹²⁰ Active substances, safeners, and synergists are approved at EU level. The same procedure¹²¹ and the same approval criteria apply to these three categories.¹²² The multi-level procedural arrangements enshrined in the Regulation provide for a draft assessment report by the Rapporteur Member State, namely the Member State which received the original application for approval,¹²³ and the engagement of the EFSA, which will adopt a final Opinion. In the Opinion, the EFSA will draw its conclusions as to whether the active substance—or safener or synergist—can be expected to meet the approval criteria.¹²⁴ The procedure will then enter the Comitology stage, with the Commission submitting its proposed draft Regulation to the relevant Committee.¹²⁵ Conversely, specific PPPs in their different formulations are authorized at *Member State level* and in the framework of the Regulation's zone system.¹²⁶ What is relevant for the purposes of the present inquiry, however, is rather an analysis of the *criteria* for EU approval of active substances and for the authorization of PPPs at Member State level, together with any relevant risk mitigation measures that EU or Member State authorities may attach to the approvals.

with Regulation 1107/2009 of the European Parliament and of the Council as regards Uniform Principles for Evaluation and Authorization of Plant Protection Products, 2013 O.J. (L 93).

¹¹⁵PPP Regulation, *supra* note 12, at art. 2(3)(a).

¹¹⁶*Id.* at art. 2(3)(b).

¹¹⁷*Id.* at art. 2(3)(c).

¹¹⁸*Id.* at art. 2(3)(d).

¹¹⁹There are no official data on the exact number of PPPs authorized across the EU. For this estimate, see EUROPEAN PARLIAMENT, REPORT ON THE UNION'S AUTHORIZATION PROCEDURE FOR PESTICIDES, (2018/2153 (INI)), at 14, pt. BU (Dec. 18, 2018).

¹²⁰PPP Regulation, *supra* note 12, art. 27(1)(a–b).

¹²¹See *id.* at arts. 5–13 for the approval procedure; *id.* at arts. 14–21 for the renewal of approval or review procedures.

¹²²For active substances, see PPP Regulation, *supra* note 12, art. 4, Annex II. For safeners and synergists, see PPP Regulation, *supra* note 12, at art. 25.

¹²³PPP Regulation, *supra* note 12, at arts. 7–11.

¹²⁴*Id.* at art. 12.

¹²⁵*Id.* at arts. 13, 78–79. The criteria to be taken into account for the purposes of deciding whether to approve or not to approve active substances are laid out in PPP Regulation, *supra* note 12, at art. 13. For more details see Leonelli, *The Glyphosate Saga and the Fading Democratic Legitimacy of EU Risk Regulation*, *supra* note 8.

¹²⁶PPP Regulation, *supra* note 12, at arts. 28, 32.

Starting from active substances, safeners, or synergists, points 3.6.2–3.6.4 and 3.7 of Annex II to the PPP Regulation include the so-called “cut-off” hazard-based criteria for approval.¹²⁷ An active substance may not be approved if it is classified as a mutagen 1A or 1B substance under the CLP Regulation.¹²⁸ Further, it may not be approved if it is classified as a carcinogen 1A or 1B¹²⁹ or toxic for reproduction 1A or 1B substance under the same Regulation¹³⁰ unless exposure to the active substance in conditions of use of PPPs containing it is negligible and the residues of the PPPs containing it are in accordance with the relevant Maximum Residue Levels (MRLs).¹³¹ By this reference already, as will be explained in detail below, it is possible to infer the partially overlapping nature of assessment of an active substance and assessment of indicative uses of representative PPPs containing the active substance. Active substances are not used on their own, but in formulations including co-constituents; different formulations result in different PPPs. For this reason, any EU-wide assessment of the risks posed by an active substance will, at least in part, be conducted by means of an assessment of the risks posed by exposure to representative PPPs containing that active substance, or by their residues.

Under the third “cut-off” criterion, an active substance may not be approved if it is considered to be a persistent organic pollutant (POP), persistent, bioaccumulative, and toxic (PBT), or a very persistent and very bioaccumulative (vPvB) substance.¹³² Turning to the following criteria, point 3.1 mandates that the applicant’s dossier should contain—where relevant—an AOEL,¹³³ acute reference dose, acceptable daily intake, and MRLs. These values refer to representative PPPs containing the active substance; under point 3.6.1, they shall be established with a safety margin of at least 100, or an increased one. Points 3.2–3.4 lay out criteria for efficacy—of the active substance and representative PPPs—metabolites and impurities. Further, point 3.6.5 specifies that an active substance may not be approved if it has endocrine disrupting properties. But again, this is so unless exposure to the active substance in conditions of use of PPPs containing it is negligible and the residues of the PPPs containing it comply with the MRLs.¹³⁴ Finally, points 3.8–3.10 provide criteria on ecotoxicology,¹³⁵ residues, and groundwater.

Pursuant to point 3.5.3 of the Annex and Article 4(4) of the Regulation, in accordance with the necessity to analyze the risks posed by active substances in light of exposure to PPP formulations containing it, the evaluation of an active substance shall be carried out in accordance with the principle for evaluation and authorization of PPPs at Member State level referred to in Article

¹²⁷ According to some accounts of EU governance of pesticides, the EU follows a “hazard-based” approach. These accounts draw on the existence of hazard-based cut-off criteria to infer that the regulatory model is “hazard-based.” In fact, “risk” is a function of the probability of occurrence of adverse effects and their severity as resulting from *exposure* to a *hazard*; clearly, where substances are highly hazardous, risks are bound to increase. As detailed in this subsection, the hazard-based cut-off criteria set a rebuttable presumption that, due to the highly hazardous properties of specific active substances, the relevant risks will not meet the intended level of protection. Mutagen substances are an exception, as they are the most hazardous of all.

¹²⁸ PPP Regulation, *supra* note 12, Annex II, pt. 3.6.2 (referring to Regulation 1272/2008 of the European Parliament and of the Council of 16 December 2008, Classification, Labelling and Packaging of Substances and Mixtures, Amending and Repealing Directives 67/548/EEC and 1999/45/EC, and Amending Regulation 1907/2006, 2008 O.J. (L 353).

¹²⁹ PPP Regulation, *supra* note 12, at Annex II, pt. 3.6.3. See also PPP Regulation, *supra* note 12, at art. 4(7), for a derogation.

¹³⁰ PPP Regulation, *supra* note 12, at Annex II, pt. 3.6.4. See also PPP Regulation, *supra* note 12, at art. 4(7), for a derogation.

¹³¹ Regulation 396/2005 of the European Parliament and of the Council of 23 February 2005, Maximum Residue Levels of Pesticides in or on Food and Feed of Plant and Animal Origin and Amending Council Directive 91/414/EEC, 2005 O.J., (L 70).

¹³² PPP Regulation, *supra* note 12, at Annex II, pt. 3.7.

¹³³ See *supra*, the analysis of *Paraquat* in Section D.

¹³⁴ PPP Regulation, *supra* note 12, at Annex II, pt. 3.6.5; A carcinogen 2 and toxic for reproduction 2 substance shall be considered to have endocrine disrupting properties, whereas a toxic for reproduction 2 substance which has endocrine disrupting organs may be considered to have endocrine disrupting properties. See also PPP Regulation, *supra* note 12, at art. 4(7), for a derogation.

¹³⁵ PPP Regulation, *supra* note 12, at Annex II, pt. 3.8. See also PPP Regulation, *supra* note 12, at art. 4(7), for a derogation.

29(6). These uniform principles are enshrined in Regulation 546/2011.¹³⁶ The interlocking nature of the two forms of assessment is further clarified by point 2.1 of the Annex and Article 4(5), providing that the two approval criteria of Article 4 are complied with when authorization in at least one Member State is expected to be possible for at least one PPP containing that active substance for at least one representative use.

Under Article 4(3), read in conjunction with Annex II, an active substance shall be approved if at least one PPP containing it, consequent on application consistent with good practice and having regard to realistic conditions of use, meets five criteria.¹³⁷ First, the PPP must be sufficiently effective. Second, it must have no immediate or delayed harmful effect on groundwater and on human health, directly or indirectly, taking into account any cumulative and synergistic effects in accordance with the EFSA's guidelines on applicable scientific methods and protocols.¹³⁸ In other words, the uncertain risks posed by the interaction of active substances and co-constituents in PPP formulations must be taken into consideration. Third, it shall not have any unacceptable effects on plants or plant products. Fourth, it shall not cause unnecessary suffering to vertebrates. Fifth, it shall not have any unacceptable effects on the environment. Under Article 4(2), read in conjunction with Annex II, the residues of the PPP containing the active substance, consequent on application consistent with good practice and having regard to realistic conditions of use, shall neither have any harmful effects on human or animal health, taking into account any cumulative and synergistic effects, nor any unacceptable effects on the environment.

This brief overview sheds some light on the highly complex evaluations underlying EU approval of pesticidal active substances. EU risk assessments are meant to encompass the hazardous properties of active substances, an analysis of their behavior when interacting with co-constituents in representative PPPs, an examination of exposures to PPPs under realistic conditions for use as well as the determination of relevant AOELs, ADIs, MRLs, and conditions for use. Both Regulation 546/2011 and Regulation 283/2013 take a prudential approach to risk assessment, requiring a comprehensive and in-depth examination and stressing that the relevant margins of uncertainty should be taken into due consideration, both in the analysis of potential hazards and in the evaluation of risk.¹³⁹ However, as further explored in the following subsections, different factors as well as multiple uncertainties come into play. The latter may relate to the identification and characterisation of specific hazards, insofar as a causal relationship between the characteristics of a product and adverse effects may not have been scientifically established; the hazards might be connected to the active substance, as such, or to the synergistic and cumulative effects of its interaction with co-formulants in PPPs. Further, predicting exposure to PPPs, the probability of occurrence of adverse effects, and their severity poses a plurality of challenges. This is not only because of the inherent difficulties in predicting exposures in realistic conditions, but also because of the varying availability and effectiveness of risk management measures—for example, good practice in the use of PPPs or appropriate equipment. The latter element adds a further layer of complexity in that it feeds into the determination that the AOELs or ADIs will be *met* and that risks will be *acceptable*, influencing the approval decision.¹⁴⁰

To conclude this first part of the overview, it is worth highlighting that conditions or restrictions may be attached to the approval of an active substance at EU level. Pursuant to Article 6, these might relate inter alia to the minimum degree of purity or impurities of the active substance, the types of preparation and formulation of PPPs, the conditions of application, the categories of users, or the areas where PPPs containing the active substance may be used. Further, restrictions

¹³⁶Commission Regulation 546/2011, *supra* note 114.

¹³⁷PPP Regulation, *supra* note 12, at art. 4(3)(a–e).

¹³⁸These have now been adopted; see REPORT ON THE UNION'S AUTHORIZATION PROCEDURE FOR PESTICIDES, *supra* note 119, at 10.

¹³⁹See Commission Regulation 546/2011, *supra* note 114; Commission Regulation 283/2013, *supra* note 114.

¹⁴⁰See *supra*, the analysis of *Paraquat* in Section D.

for use may be provided in case of specific agricultural, plant health, or environmental and climatic conditions, and ad hoc risk mitigation and monitoring conditions may be attached.

These can, and should, be complemented by further conditions and restrictions adopted at Member State level within the authorization of single and specific PPPs containing the active substance.¹⁴¹ National authorizations of PPPs shall define plants or plant products and the purposes for which the PPP may be used, including non-agricultural areas on which it may be used and the requirements relating to its placing on the market.¹⁴² Where applicable, the authorization shall include the maximum dose per application and the maximum number of applications and relevant timeframes; it may also list further restrictions or conditions.

In their risk assessment of specific PPPs, Member States should apply the uniform principles of Regulation 546/2011 and focus on the hazards and specific risks posed by interaction between the active substance, safeners, synergists, and co-formulants.¹⁴³ Adjuvants, preparations to be mixed with PPPs, are also authorized at Member State level.¹⁴⁴

Article 29(1) provides a list of requirements to be met for authorization of specific PPPs,¹⁴⁵ including that any PPP shall comply with the requirement of Article 4(3),¹⁴⁶ that its formulation is such that exposure or other risks are limited as much as technically possible,¹⁴⁷ and that its residues of toxicological, ecotoxicological, or environmental relevance can be determined and limited.¹⁴⁸ All tests and analyses must be carried out under the agricultural, plant health, and environmental—including climatic—conditions prevailing in the specific zone and Member State, taking into account realistic conditions of use and proper use under Article 55.¹⁴⁹ Indeed, the allocation of responsibility for the authorization of specific PPPs to the Member States responds—at least in part—to the principle of subsidiarity.¹⁵⁰

Yet again, the PPP Regulation and implementing acts provide for a thorough and *prudential* risk assessment of PPPs at Member State level. This is complemented by the express possibility for Member States to resort to *precautionary* risk management, in the face of persisting uncertainty, and to decide *not* to authorize PPPs, despite the prior approval of active substances at EU level. Article 1(3) and 1(4) provide that the purpose of the PPP Regulation is to ensure a high level of public health and environmental protection, and that the Regulation is underpinned by the precautionary principle. Article 1(4) expressly maintains that “Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks . . . posed by the [PPPs] to be authorized in their territory.”¹⁵¹

This is reflected in the procedures of Articles 36 and 50. Pursuant to Article 36(2), Member States shall grant or refuse authorizations on the grounds of the results of risk assessment; under Article 36(3), they may impose appropriate conditions or risk mitigation measures. Further, where a

¹⁴¹PPP Regulation, *supra* note 12, at art. 31(2). At a minimum, the Member State Authorization Act shall include all conditions established at EU level in the act approving the relevant active substances, safeners, and synergists.

¹⁴²PPP Regulation, *supra* note 12, at art. 31(1–2).

¹⁴³*Id.* at art. 29(6). The data requirements for the applicants are laid out in Commission Regulation 284/2013 of 1 March 2013 Setting Out the Data Requirements for Plant Protection Products, in Accordance with Regulation 1107/2009 of the European Parliament and of the Council Concerning the Placing of Plant Protection Products on the Market, 2013 O.J. (L 93). Regrettably, the harmonized guidelines on applicable scientific methods and protocols for the evaluation of PPPs at Member State level, referenced in PPP Regulation, *supra* note 12, at art. 29(4) are yet to be adopted by the EFSA; see REPORT ON THE UNION'S AUTHORISATION PROCEDURE FOR PESTICIDES, *supra* note 119, at 26, pt. 91.

¹⁴⁴PPP Regulation, *supra* note 12, at art. 58.

¹⁴⁵For the full list, see the text of PPP Regulation, *supra* note 12, at art. 29(1). Clearly, the relevant active substances, safeners, and synergists must have been approved at EU level; the relevant co-formulants must have not been banned.

¹⁴⁶PPP Regulation, *supra* note 12, at art. 29(1)(e).

¹⁴⁷*Id.* at art. 29(1)(d).

¹⁴⁸*Id.* at art. 29(1)(g).

¹⁴⁹PPP Regulation, *supra* note 12, at art. 29(3). See also PPP Regulation, *supra* note 12, at arts. 36(1), 55.

¹⁵⁰See PPP Regulation, *supra* note 12, at recital (23); see also, *infra*, Section F(II).

¹⁵¹PPP Regulation, *supra* note 12, at art. 1(4).

Member State has substantiated reasons to consider that a PPP—due to specific agricultural or environmental circumstances—poses an unacceptable risk to human or animal health or the environment, which cannot be adequately controlled by the establishment of national risk mitigation measures, it is entitled to refuse authorization.¹⁵² Moreover, Article 50(2) stipulates that Member States may in exceptional cases refuse an authorization if a non-chemical control or prevention method exists for the same use and is in general use in that Member State.¹⁵³ The precautionary principle and the principle that a high level of public health and environmental protection should be pursued shine through these clauses. Additional safeguards are stipulated by Article 44—providing that authorizations may be reviewed, withdrawn, or amended at any time where the criteria of Article 29 are no longer met—as well as Articles 69, 70, and 71, which all contain emergency measures.

Against the overall backdrop of this overview, the next subsection analyzes the Advocate General and the Court's line of reasoning, explaining on which grounds the referring court raised the issue of compliance with the precautionary principle in the framework of the PPP Regulation. This is followed by an examination of the gap between regulation and regulatory implementation in the field of pesticides, as developed in Subsection F(II). The analysis shows how the Court's ruling in *Blaise* did not, and in fact could not, do justice to the points raised by the parties in the national proceedings.

I. Judicial Review of EU Legislative Acts (II): *Blaise*

The national court referred four questions for a preliminary ruling, each of which surrounded the PPP Regulation's governance arrangements and their compliance with the precautionary principle. This reference arose in the context of criminal proceedings against a group of French anti-genetically engineered organisms activists who had been charged with degrading or deteriorating property after defacing containers of glyphosate-based herbicides. Thus, this reference is set against the much broader background of the glyphosate re-approval controversy.¹⁵⁴ As Advocate General Sharpston noted in her preliminary considerations:

[T]he validity of provisions of EU law is to be assessed according to the characteristics of those provision themselves and cannot depend on the particular circumstances of a given case. . . . Unless concerns relating to glyphosate are shown to be representative of a systemic and fundamental failure undermining the PPP Regulation [and its aims], they cannot place in doubt the overall integrity of the prior approval system established by the Regulation.¹⁵⁵

With this statement she drew some clear boundaries between issues pertaining to the PPP Regulation's governance arrangements, on the one hand, and issues relating to the implementation of the PPP Regulation in the specific case of glyphosate, on the other hand. However, the gap between regulation and regulatory implementation permeates the entire case; in fact, as the next subsection explains, this gap goes well beyond the specifics of glyphosate's re-approval, which only provided the setting for the reference by the national court.

¹⁵²*Id.* at art. 36(3).

¹⁵³The text of this Article is not totally clear, given that Article 50(1) on the comparative assessment procedure in case of PPPs containing an active substance which is a candidate for substitution is broader in scope. Not only does it refer to non-chemical alternatives, but also to any prior authorization of a significantly safer PPP which can fulfil the same function, and does not present significant economic or practical disadvantages.

¹⁵⁴For more information, see Leonelli, *The Glyphosate Saga and the Fading Democratic Legitimacy of EU Risk Regulation*, *supra* note 8.

¹⁵⁵Opinion of Advocate General Sharpston at para. 44, Case C-616/17, *Blaise and Others* (Mar. 12, 2019).

After this introductory remark, she provided a very brief overview of the precautionary principle's application to judicial review,¹⁵⁶ noting that the referring court did not "explain what it understands to be the components of the principle or indicate to what extent that principle is to be applied by the Court when considering whether an EU measure . . . is invalid."¹⁵⁷ The Advocate General remarked that the PPP Regulation is in and of itself a precautionary measure, in that it establishes a system of prior approval for pesticidal products, and that it is underpinned by the precautionary principle. Thus, the measures adopted under it should be based on the precautionary principle.¹⁵⁸ However, she also noted that a correct application of the precautionary principle postulates an identification of potential adverse effects as well as a comprehensive risk assessment.¹⁵⁹ To elaborate further, and as explained above, the risk assessment provided for under EU legislative acts should be robust enough to enable risk managers to exercise their discretion and adopt precautionary risk management measures where scientific uncertainty persists and uncertain risks might not comply with the intended level of protection. Against this backdrop, the Advocate General summarized the four questions of the national court by noting that all of them point to "generic failures in the overall system of risk assessment of [PPPs, insofar as] the assessment is insufficiently comprehensive (Questions 1, 3 and 4) or independent and transparent (Question 2)."¹⁶⁰

The Opinion and the Judgment frame the question of compliance with the precautionary principle in terms of whether the EU legislator, by enacting legislative provisions in breach of the precautionary principle, incurred a manifest error of assessment.¹⁶¹ As already explained in Section C, this test does not quite do justice to review of compliance with the precautionary principle in cases where acts are challenged for *not* being *protective enough*. In these cases, the precautionary principle should be framed as an inner limit to administrative or political discretion. However, in the context of the present analysis, it is worth mentioning that the Advocate General and Court's choice to focus on whether the PPP Regulation arrangements are vitiated by a manifest error did not influence the examination of the relevant provisions or the outcome of the ruling.

By its first question, the national court inquired whether the PPP Regulation is compatible with the precautionary principle insofar as it provides no specific definition of an active substance, leaving it to the applicant to determine what it designates as the relevant active substance whereas PPPs placed on the market are made up of several co-constituents. By its third, somewhat oddly framed question, the referring court ultimately asked whether the PPP Regulation is compatible with the precautionary principle when it provides for EU approval of active substances and takes no account of the presence of co-constituents in PPPs. These questions point to the multi-level dynamics underlying the regulatory framework. By its questions, the referring court meant to inquire whether the bifurcated system of the PPP Regulation enables the relevant authorities to take into due consideration the potential interaction of active substances and co-constituents in different PPP formulations.

In the first respect, the Advocate General found that, under Article 2(2), any substance having "general or specific action against harmful organisms or on plants, parts of plants or plant products" is considered an active substance subject to the data requirements of Regulation 283/2013 and approval conditions of the PPP Regulation.¹⁶² In scientific terms, as already explained, active

¹⁵⁶This part of the Opinion, for instance, does not reference *Monsanto Italia*—the only case before *Blaise* where the Court examined compliance with the precautionary principle of a legislative act indirectly challenged for being insufficiently protective.

¹⁵⁷Opinion of Advocate General Sharpston, *supra* note 155, at para. 47.

¹⁵⁸*Id.* at paras. 44, 50.

¹⁵⁹*Id.* at para. 48; *see also* Judgement at paras. 46, 47.

¹⁶⁰Opinion of Advocate General Sharpston, *supra* note 155, at para. 51.

¹⁶¹*Id.* at paras. 50, 51, 52.

¹⁶²*Id.* at para. 55.

substances are acknowledged to be the main pesticidal components of a PPP, as distinguished from any potential co-constituents. Further criteria for their identification are laid out in the Annex to Regulation 283/2013. The Court adhered to the Opinion.¹⁶³ In the second respect, drawing on the relevant legislative provisions,¹⁶⁴ both the Advocate General and the Court found that the PPP Regulation requires the potential effects of interacting co-constituents in PPP formulations to be taken into account *both* at EU level—in the procedure for authorization of active substances—and at Member State level, in the national procedure for authorization of PPPs containing that active substance.¹⁶⁵ The Court noted that “it is inherent in [the assessment of an active substance at EU level] that [such assessment] cannot be carried out in an objective fashion while failing to take into account the effects derived from a possible combination of various constituents of a [PPP].”¹⁶⁶ As explained earlier in Section F, active substances are not used on their own, but in PPPs containing other co-constituents. For this reason, when assessing the risks of an active substance, the relevant authorities must also take into account *representative PPPs* containing that *active substance*. The opposite would not make any sense in scientific terms. On these grounds, the Court concluded that no manifest errors could be identified.

By its second question, which is partly relevant for the purposes of the present analysis, the national court inquired whether the precautionary principle is observed and impartiality maintained when the relevant scientific tests are conducted by the applicants alone, without any independent counter-analysis.¹⁶⁷ This question is clearly set against the broader backdrop of the glyphosate saga. Notably, the controversies arising from excessive reliance by the national competent authority in the Rapporteur Member State on data provided in the applicant’s dossier, the “Monsanto Papers” scandal, allegations of conflict of interest and lack of transparency within the EFSA, and the request by the Stop Glyphosate European Citizens Initiative to provide that scientific tests, studies, and analyses should not be conducted or provided by market applicants but instead by regulatory agencies.¹⁶⁸

The regulatory presumption that a product or process should be deemed *unsafe* until market applicants have proven that it is *safe enough* for its risks to comply with the EU intended level of protection is encoded in the DNA of EU risk regulation;¹⁶⁹ so is the presumption that the *scientific burden of proof* rests with the market applicants.¹⁷⁰ While this is by no means an ideal scenario, insofar as information asymmetries may surface and scientific data may be manipulated by market applicants, it responds to administrative and economic needs. Most importantly, it reflects the principle that market applicants who will economically profit from the authorization of a product should bear the economic costs associated with the authorization procedure and have responsibility for producing the relevant scientific evidence.¹⁷¹ On these grounds, the relevant question is rather whether sufficient procedural safeguards, notably adequate research, reliance on broader peer reviewed studies, and an independent counter-analysis by regulatory agencies, are in place.

¹⁶³See the more detailed examination in the Opinion of Advocate General Sharpston, *supra* note 155, at paras 52–61.

¹⁶⁴PPP Regulation, *supra* note 12, at art. 4(1–5), 4(2,3), 29(6), 25, & 27.

¹⁶⁵Opinion of Advocate General Sharpston, *supra* note 155, at paras. 56–61, 62–76.

¹⁶⁶*Id.* at paras. 68.

¹⁶⁷This question included reference to whether the precautionary principle is complied with in the absence of publication of the application dossiers “on the pretext of protecting industrial secrecy.” This aspect is not taken into consideration, as it is unrelated to the analysis of compliance with the precautionary principle; in other words, it is irrelevant to the question whether the risk manager is endowed with all information necessary to enact precautionary risk management measures. Rather, this part of the question touches upon matters of transparency and access to documents.

¹⁶⁸For more information, see Leonelli, *The Glyphosate Saga and the Fading Democratic Legitimacy of EU risk Regulation*, *supra* note 8.

¹⁶⁹*Id.*

¹⁷⁰See, e.g., *Commission Communication on the Precautionary Principle*, *supra* note 14, at 20, § 6.4. See PPP Regulation, *supra* note 12, at arts. 7(1), 29(2).

¹⁷¹*Commission on the European Citizens’ Initiative Ban Glyphosate and Protect the People and the Environment from Toxic Pesticide*, at 10, § 3.2, COM (2017) 8414 final (Dec. 12, 2017).

The independence and accountability of regulatory agencies and the transparency of the risk assessment process also come into play.

The Advocate General found in her Opinion that “*if the rules are followed*, [scientific data provided under the PPP Regulation] will be of a certain standard set by that Regulation and its related secondary legislation.”¹⁷² The Court took a similar perspective. Tests and analyses must be conducted according to the rules on good laboratory practice, as provided for under the Good Laboratory Practice Regulation;¹⁷³ further specifications are laid out in the PPP Regulation.¹⁷⁴ Specific data requirements for both active substances and PPPs are enshrined in the 2013 Regulations,¹⁷⁵ and further guidelines on scientific methods and protocols for the evaluation of active substances have been adopted by the EFSA. Scientific, peer-reviewed literature must also be adduced by the applicants and reviewed by the agencies.¹⁷⁶ Where the relevant agencies are not satisfied that the data is sufficient to grant approval or an authorization, they are under an obligation to request additional information.¹⁷⁷ Further, the involvement and engagement of different agencies across the EU, in accordance with the multi-level arrangements of the PPP Regulation, acts as a safeguard by enabling different authorities to review the relevant data.¹⁷⁸ In light of this examination, both the Advocate General and the Court concluded that the PPP Regulation is not vitiated by a manifest error of assessment in this respect.

Finally, by its last question, the national court asked whether the PPP Regulation is compatible with the precautionary principle insofar as it exempts from toxicity tests—genotoxicity, carcinogenicity, and endocrine disruption effects—PPPs authorized at the national level. These tests are required for the purposes of authorizations of active substances;¹⁷⁹ however, no such obligation is in place for the purposes of national authorizations of PPPs. In her Opinion, the Advocate General stressed that under Regulation 284/2013, national authorities have the express power to request additional data, including toxicity studies. On these grounds, she ultimately concluded that no manifest error of assessment could be identified in the regulatory arrangements.¹⁸⁰ In a slightly different way, the Court emphasized that under Articles 4(3)(b) and 29(1)(e), a PPP can only be authorized if it has no immediate or delayed harmful effects. This presupposes that the national authorities must exclude any toxic effects prior to authorization.¹⁸¹ It thus concluded that the examination of the questions referred had not revealed elements capable of affecting the validity of the PPP Regulation.

Against this overall backdrop, the next section explores the gap between regulation and regulatory implementation which lies at the heart of *Blaise* and the questions referred by the national

¹⁷²Opinion of Advocate General Sharpston, *supra* note 155, at para. 64 (emphasis added). See also Opinion of Advocate General Sharpston, *supra* note 155, at para. 69:

... [T]he system of structured assessment at EU and Member State levels laid down by the PPP Regulation is both appropriate and sufficient to achieve the high level of environmental and human health protection sought. If correctly applied, that regulatory system will generate a comprehensive risk assessment that can be relied upon by the competent authorities to justify adopting precautionary measures where appropriate.

¹⁷³Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004, Harmonization of Laws, Regulations, and Administrative Provisions relating to the Application of the Principles of Good Laboratory Practice and the Verification of their Applications for tests on Chemical Substances, 2004 O.J. (L 50).

¹⁷⁴See PPP Regulation, *supra* note 12, at art. 8.1, Annex I, 29(3), as noted in Opinion of Advocate General Sharpston, *supra* note 155, at paras. 82–85.

¹⁷⁵See Annexes to Commission Regulation 283/2013 & 284/2013, pt. 3, *supra* notes 114 & 143, as also noted in the Opinion of Advocate General Sharpston, *supra* note 155, at para. 87.

¹⁷⁶As stipulated by PPP Regulation, *supra* note 12, at art. 8(5); see Opinion of Advocate General Sharpston, *supra* note 155, at paras. 65, 89, 93–94.

¹⁷⁷See PPP Regulation, *supra* note 12, at art. 11(3), 12(3), 37(1), as noted in Opinion of Advocate General Sharpston, *supra* note 155, at para. 92.

¹⁷⁸See Opinion of Advocate General Sharpston, *supra* note 155, at paras. 66–68, 96–98.

¹⁷⁹See PPP Regulation, *supra* note 12, at Annex I; Commission Regulation 283/2013, *supra* note 114, at § 5.

¹⁸⁰Opinion of Advocate General Sharpston, *supra* note 155, at para. 79.

¹⁸¹Opinion of Advocate General Sharpston, *supra* note 155, at paras. 113–16.

court. In this context, and with a particular focus on the multi-level risk assessment of active substances and PPPs, it explains how the Court did not—and in fact could not—judicially review the problematic aspects underlying the PPP Regulation’s governance arrangements in light of the precautionary principle.

II. Judicial Review of EU Legislative Acts (II): The Gap Between Regulation and Regulatory Implementation in *Blaise* and the Inadequacy of the PPP Regulation Arrangements. Active Substances and PPPs

Were the referring court’s questions on compliance with the precautionary principle, as referred by the national court in *Blaise*, so easy to answer? Admittedly, they were not. In fact, some problematic aspects surrounding the *implementation* of the multi-level arrangements enshrined in the PPP Regulation, the comprehensiveness and thoroughness of the risk assessments conducted to approve active substances and authorize PPPs, and their ability to inform the knowledge of risk managers with a view to enabling *precautionary* risk management, can be easily identified.

The imperfect balance between EU assessment and approval of active substances, on the one hand, and partially overlapping Member State assessments and authorizations of PPPs, on the other hand, is ultimately based on the need to distribute authority and share technical-scientific and administrative burdens. Subsidiarity plays a role in the allocation of responsibility for authorizing PPPs at Member State level. The agricultural, plant health, and environmental-climatic conditions prevailing in the specific zone and Member State, taking into account realistic conditions of use and proper use, must be duly evaluated for the purposes of deciding whether a PPP should be authorized and whether further risk mitigation measures should be put in place. However, acknowledging that Member States should have the final word on *authorizations* of PPPs on their territory does not necessarily mean that they should be in charge for their *risk assessment*.¹⁸² In terms of regulatory implementation, the bifurcated system of the PPP Regulation poses a plurality of challenges.

The EU level conducts some form of preliminary or indicative evaluation of the risks posed by exposure to active substances as contained in *representative PPP formulations*; this can by no means provide an exhaustive risk assessment of all cumulative and synergistic effects for each and every PPP containing that active substance which will be placed on the market. On the one hand, EU assessments of active substances are not limited to an evaluation of the risks associated with the single and specific substance. As explained in Section F, they do encompass an analysis of the risks posed by the use or residues of PPP formulations containing it. On the other hand, it is fair to stress that these assessments do not give the full picture of the public health and environmental risks posed by different pesticidal products containing the active substance, as the specific co-constituents or their relative quantities may vary in every PPP. Indeed, if the opposite were the case, there would be no reason to provide for risk assessment of PPPs at Member State level.

In other words, EU assessments provide an indication that pesticides containing an active substance *should* be safe. The detailed assessment of the specific pesticidal formulations will then be conducted at Member State level. From this perspective, the distinction between risk assessment of *active substances as contained in PPPs* and risk assessment of *PPPs* is somewhat artificial. More importantly, the determination that an active substance should be safe, even though it might not always be so in specific pesticidal products, is problematic. Arguably, this is what the referring court suggested in its first and third questions.

Further, it is worth stressing again that multiple uncertainties come into play in the field of pesticides. As briefly mentioned in Section F, several uncertainties surface in the evaluation and characterisation of risks. Uncertainty may arise because of the inherent difficulties in predicting exposure in realistic conditions. The availability and effectiveness of risk mitigation measures—for instance good practice in the use of PPPs, or appropriate equipment—will also influence the risks that

¹⁸²On this point, see *infra*, the discussion later in this subsection.

pesticidal formulations pose in practice. In this context, the identification and determination of public health and environmental hazards by means of a *partial* analysis of synergistic and cumulative effects of active substances and co-constituents at EU level adds up to this complex picture.

Indeed, a 2018 Report of the European Parliament makes three very important points in this respect. First, it expressly calls on the Commission to ensure that active substances are assessed on the basis of the most frequent relevant *uses, PPP formulations, dosages, and exposure scenarios*.¹⁸³ Second, it recommends that an extra safety factor should be applied when calculating the AOELs to address the potential toxicity of mixtures in PPP formulations.¹⁸⁴ Third, it remarks that the “harmful” and “unacceptable” effects provided for under Article 4(2) and (3) should be determined by taking into account real-life exposure to multiple PPPs.¹⁸⁵ This last point is addressed in greater detail below.

Can the partially overlapping risk assessment of PPPs at Member State level remedy this gap, giving a full picture of the risks posed by single PPP formulations and thus enabling national risk managers to enact precautionary measures and pursue a high level of protection? Overall, it does not look like this is the case. Regulatory and institutional capacity is inferior at the national level, and divergences between Member States can be significant in this respect. The European Parliament Special Committee on the Union’s authorization procedure for pesticides has lamented that national competent authorities are under-staffed and under-funded.¹⁸⁶ On these grounds, if something has slipped through the cracks of the preliminary evaluation at EU level, it is highly likely that it will also slip through the cracks at Member State level. Further, the European Parliament has identified a plurality of shortcomings in risk assessments conducted at Member State level. First, and most worryingly, national authorities excessively rely on EU risk assessments of the relevant active substances for the purposes of reaching their conclusions on PPPs containing these active substances, extrapolating data from the EFSA’s conclusions.¹⁸⁷ Highly hazardous pesticides may then be marketed on the grounds of a *preliminary* EU assessment of the behavior of an active substance in pesticides and an *insufficient* national assessment of individual PPPs. Second, national risk assessments of PPPs too often fail to take account of realistic conditions of use and exposure.¹⁸⁸ As explained above, this generates a number of highly relevant uncertainty factors. Third, as the defendants in the national proceedings in *Blaise* rightly remarked, no obligation for an assessment of the long-term toxicity of PPPs is laid out in Regulation 284/2013.¹⁸⁹ The Report calls on the Commission to remedy this situation.¹⁹⁰

On these grounds, in practical terms, the problems associated with the *implementation* of the PPP Regulation may not enable EU or national risk managers to take adequately informed decisions, pursuing a high level of protection and resorting to the precautionary principle where recourse to it is warranted. Risk assessment of pesticidal formulations, at the EU as well as at the national level, is thus *not comprehensive enough* to do justice to a correct application of the precautionary principle. In fact, issues of *risk management* and *risk mitigation* make this picture even more complex. These elements include the reluctance of national authorities to

¹⁸³REPORT ON THE UNION’S AUTHORISATION PROCEDURE FOR PESTICIDES, *supra* note 119, at 21.

¹⁸⁴*Id.* at 23.

¹⁸⁵*Id.* at 24.

¹⁸⁶*Id.* at 7, 14. On this matter, see also European Parliament Resolution of 13 September 2018 on the Implementation of the Plant Protection Products Regulation 1107/2009, (2017/2128(INI)) pt. 38.

¹⁸⁷REPORT ON THE UNION’S AUTHORISATION PROCEDURE FOR PESTICIDES, *supra* note 119, at 14, 26.

¹⁸⁸*Id.* at 14.

¹⁸⁹*Id.* at 15.

¹⁹⁰*Id.* at 22. This situation is exacerbated by further problematic aspects, which, however, are unrelated to the issues at stake in *Blaise*. First, the Commission is yet to adopt a list of approved safeners and synergists; on this point, see also REPORT ON THE UNION’S AUTHORISATION PROCEDURE FOR PESTICIDES, *supra* note 119, at 15, 25. Second, the EU has not yet adopted a list of banned co-formulants; the relevant consultations only closed in February 2020, and the Commission Regulation is still in draft form. Third, as mentioned *supra* in note 143, harmonized guidelines on methods and protocols for the evaluation of PPPs at Member State level are yet to be adopted by the European Food Safety Authority (EFSA).

supplement the risk mitigation measures provided for in the EU approval of active substances,¹⁹¹ the limited implementation and limited effectiveness of risk mitigation measures at Member State level,¹⁹² and the patchy implementation of the Sustainable Use of Pesticides Directive.¹⁹³ The latter enshrines a set of obligations relating to risk management; these encompass risk reduction strategies through raising information and awareness, requirements for the sale of pesticides, inspections on pesticide application equipment, limitations on specific application practices, the enactment of National Action Plans and quantitative pesticide use or risk reduction targets, and the promotion of integrated pest management.¹⁹⁴ All of these measures aim at limiting exposure and managing risks posed by *single PPPs* as well as *multiple PPPs*. Implementation at the national level has been poor, particularly in the areas involving management of the risks posed by multiple PPPs.¹⁹⁵ Indeed, the Stop Glyphosate ECI called on the Commission to adopt binding pesticide use reduction targets.¹⁹⁶

Against this overall backdrop, we can conclude that EU governance of pesticides does not always live up to the overarching tenets of the precautionary principle. The *implementation* of the regulatory arrangements for risk assessment of PPPs, as laid out in the PPP Regulation, does not always comply with the precautionary principle. As clearly shown in this section, the implementation of this system may not provide an exhaustive assessment of the relevant risks, enabling precautionary risk management. This sheds some light on the interplay of complex *regulatory arrangements* and their *implementation* across different territorial levels; in other words, the analysis of the PPP Regulation shows the gap between the provisions of a regulatory framework and their implementation.

The implementation of a legislative framework and its relationship to precautionary risk management, however, is neither a matter of law nor an object of judicial review. Clearly, the differences between regulatory and legislative acts and the different form of scrutiny conducted by the Court come into play. Questions of regulatory implementation in a challenge against a legislative act are by necessity exempt from review of compliance with the precautionary principle, or any other principle. This holds true for the defendants' claims on lack of transparency of the risk assessment process as well.¹⁹⁷ The gap between law and policy cannot be bridged.

In *Monsanto Italia* and *Confédération Paysanne*, the referring courts raised *legal* questions surrounding *legal* provisions on the preconditions for a risk assessment and the scope of application of a legislative act. The connection between the specific legislative arrangements and the questions on their compliance with the precautionary principle was also quite direct. In a different vein, the national court in *Blaise* ultimately pointed to an implementation failure. As illustrated in this section, this implementation failure goes well beyond the specific circumstances of glyphosate's re-approval. The Court, however, did not have any *legal* underpinnings to find that the PPP Regulation's *legal* arrangements are insufficient to allow for precautionary risk management.

¹⁹¹REPORT ON THE UNION'S AUTHORISATION PROCEDURE FOR PESTICIDES, *supra* note 119, at 14, 25. For this reason, the Report calls on the Commission to set stringent risk mitigation measures when approving active substances.

¹⁹²REPORT ON THE UNION'S AUTHORISATION PROCEDURE FOR PESTICIDES, *supra* note 119, at 9.

¹⁹³Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 Establishing a Framework for Community Action to Achieve the Sustainable Use of Pesticides, 2009 O.J. (L 309) 1.

¹⁹⁴See respectively, *id.* at arts. 5, 7, 6, 8, 9–13, 4, 15, 16, 14.

¹⁹⁵See Report on the Implementation of Directive 2009/128/EC on the Sustainable Use of Pesticides, (2017/2284 (INI)), at 12–14 (Jan. 30, 2019), https://www.europarl.europa.eu/doceo/document/A-8-2019-0045_EN.html.

¹⁹⁶The Commission refused. For more details, see Leonelli, *The Glyphosate Saga and the Fading Democratic Legitimacy of EU Risk Regulation*, *supra* note 8. It was only in 2019 that the EU harmonized indicators on the risks posed by different active substances were adopted; see Commission Directive 2019/782 of 15 May 2019 Amending Directive 2009/128/EC of the European Parliament and of the Council as Regards the Establishment of Harmonised Risk Indicators, 2019 O.J. (L 127) 4.

¹⁹⁷This has been partially remedied by the provisions enshrined in Regulation 1381/2019 of the European Parliament and of the Council of 20 June 2019 on the Transparency and Sustainability of the EU Risk Assessment in the Food Chain and Amending Regulations (EC) 178/2002, (EC)1829/2003, (EC) 1831/2003, (EC) 2065/2003, (EC) 1935/2004, (EC) 1331/2008, (EC) 1107/2009, (EU) 2015/2283, and Directive 2001/18/EC, 2019 O.J. (L 231) 1.

As a matter of law, the Regulation complies with the precautionary principle. Issues of implementation and questions surrounding the distribution of authority between the EU and Member State level will then have to be dealt with in political fora. As the Advocate General noted in the post-script to her opinion, it will be open to political institutions to improve regulatory frameworks through the legislative process.¹⁹⁸

G. Conclusions: Mixed Results and the True Nature of the Precautionary Principle

This Article has analyzed judicial review of compliance with the precautionary principle, taking into consideration direct and indirect challenges to regulatory as well as legislative acts. Section B framed the precautionary principle as an inner limit to the EU risk manager's and legislator's broad administrative discretion. This Article has put forward this argument by contextualizing recourse to the precautionary principle against the more encompassing backdrop of socially acceptable risk approaches. Section C illustrated the challenges associated with judicial review of compliance with the precautionary principle.

Building on this overview, Section D analyzed challenges involving regulatory acts, arguing that the Court has followed a quantitative threshold approach. This is legally tenable and appropriate. Through this quantitative threshold approach, the Court has drawn some boundaries between judicial review of *compliance with the precautionary principle*, on the one hand, and an acknowledgment of the risk manager's *discretion in complying* with the precautionary principle, on the other hand. However, as also noted above, this approach cannot do justice to the true nature of the precautionary principle. Normative and political contestation as to whether uncertain risks are socially acceptable and worth running lie at the heart of principle; yet, the Court will refrain from engaging with this aspect. This is the slippery slope of the precautionary principle that the Court has carefully—and understandably—avoided.

Sections E and F turned to an analysis of preliminary rulings on the validity of EU legislative acts. In the first case under analysis, *Monsanto Italia*, the Court ultimately hesitated to intrude in the prerogative sphere of action of the legislator; it refrained from thoroughly scrutinizing whether the procedural arrangements underlying the old system for governance of genetically engineered organisms did not comply with the precautionary principle, leaving it to the EU legislator to rework the regulatory framework. In the second case, *Confédération Paysanne*, the Court was more proactive. It provided a teleological interpretation of the 2001 Directive on the Deliberate Release of genetically engineered organisms, interpreting its provisions in light of the precautionary principle, and thus avoiding an examination of the alleged invalidity of the mutagenesis exemption. Nonetheless, it is worth underlining that the Court had a set of legal elements available to underpin and substantiate its own interpretation. Finally, in *Blaise*, issues of regulatory implementation were more salient than regulatory matters. The Court limited its scrutiny to matters of law, concluding that the Regulation complies with the precautionary principle; nor could it do otherwise.

All in all, it would be excessive to say that the Court has been reluctant to review legislative acts in the field of EU risk regulation. However, the Court will find that a legislative act is in breach of the precautionary principle only where it has robust *legal* elements to draw this conclusion. In this sense, the Court has suggested that issues pertaining to procedural regulatory arrangements, the scope of risk assessment, or the distribution of regulatory authority should be primarily dealt with

¹⁹⁸See *Blaise*, Case C-616/17 at paras. 82, 83. Indeed, the 2018 Report of the European Parliament expressly calls on the Commission to consider whether the EFSA should be responsible for risk assessment of PPPs, while clarifying that risk management and decisions on authorization should still rest with Member States. Indeed, it is worth underlining that responsibility for risk assessment of PPPs could be shared between Member States, within the existing zonal system, and the EFSA. This would mirror the existing EU-wide arrangements for approval of active substances; further, it would incorporate the specific agricultural, plant health, and environmental-climatic conditions within the relevant assessments.

by the EU legislator and solved in the political arena. Ultimately, it will fall on the EU legislator to amend or improve regulatory frameworks.

Against this overall backdrop, judicial review in cases where the precautionary principle has been used as a sword is fraught with difficulties and has yielded mixed results. Qualitative disagreements on the threshold of acceptable risk will have to be solved in the political arena. In this sense, the inner limits to the exercise of the risk manager's broad administrative discretion are quite thin. Equally, several obstacles to the Court's examination in cases involving legislative arrangements may surface, limiting the chances for a legal finding that they are in breach of the precautionary principle. All of these *legal* difficulties are inherent to the nature of the principle.

On these grounds, it is fair to conclude that only *regulatory* applications, *normative* contestation as to the determination of the threshold of acceptable risk and *political* and *societal* debate on the adequacy of legislative frameworks will truly do justice to the precautionary principle. A socially acceptable risk is reflected in the institutional architecture of EU governance and encoded in the DNA of EU risk regulation. Yet, it will ultimately rest on EU risk managers and EU legislators to ensure that the overarching goals of the precautionary principle are pursued. While the principle has legal relevance for the purposes of judicial review, the Court cannot be expected to fill the vacuum of regulatory authority.